Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 1)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is:

When individuals are fitted with new hearing aids, the function of the hearing aids in the listener's real ear is tested using specialized equipment (procedure called real-ear verification), requiring the patient to be present at the fitting. The purpose of this study is to determine if a simulated hearing-aid fitting approach (simulated real-ear verification) that does not require a visit is as good as the standard face-to-face hearing-aid fitting approach for experienced hearing-aid users getting new hearing aids.

You are being asked to participate in this research study because you are an experienced VA hearing aid user getting new (replacement) hearing aids that are the same style as your current hearing aids.

In this study, there will be two groups of participants, each containing 29 people. One group will be receiving replacement in-the-ear (ITE) style hearing aids and the other group will be receiving replacement behind-the-ear style (BTE) hearing aids.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental portion of this study focuses on the way in which the hearing aids are fitted (in a text box with you NOT present at a face-to-face visit) and sent to you (in the mail).

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study, then you will have two face-to-face visits completed at the MOSCH Lab at Hock Plaza at 2424 Erwin Road, Suite 103, Durham, NC 27705. Even though this is a VA study, the data collection will occur at this Duke Lab.

Visit 1 (Face-to-Face). We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). All participants will have a comprehensive hearing test. We will test your middle ear function by placing a rubber probe tip in your ear canal. You will feel pressure and may hear loud beeping. You will wear earphones and

listen for soft beeping sounds. You also will repeat words in quiet and noise. We will make sound measurements of your ear acoustics using a small probe tube in your ear canal along with a foam tip. You will complete a memory like test to ensure you meet the study criteria. We will clean and maintain your current hearing aids. We will make measurements of your current hearing aids and earmolds (e.g., earmold vent size) and ensure they are working properly and programmed to your latest hearing test. We will verify the hearing-aid function by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of the hearing aid in response to sound (beeps, noises, and/or speech). In addition, we will ask you several questions about your current hearing-aid knowledge to ensure that you can change your batteries, clean your hearing aids, etc. and ask you to demonstrate these skills. You will complete several hearing-aid outcome measures about your current hearing aids and their performance. You also will be asked how you would like your new hearing aids programmed. You also may get earmold impressions made of your ears for new earmolds. Impressions are made by putting a small foam block in your ear canal and filling it with putty-like material for about 5 minutes. This visit is estimated to last ~120 minutes.

"Visit 2". You will **NOT** come to the lab for your hearing-aid fitting. We will fit and program your hearing aids based on the measurements we made from you and your ears at Visit 1 as well as based on the several questions we asked you at Visit 1. We will verify the fit of your hearing aids in a "test box" that simulates your real ear acoustics. We will mail you your hearing aids along with your manufacturer user manual and programming report from the hearing-aid software.

You will be encouraged to wear their new hearing aids over a 4-week trial until you are seen for Visit 3.

Phone Call. All participants will receive a phone call approximately 2 days after the hearing aids are received in the mail. We will ask questions about the physical comfort of the hearing aids, sound quality, and any other hearing-aid problems. We also will answer any questions you may have about your new hearing aids. This phone call should last < 10 minutes.

Visit 3 (Face-to-Face). All participants will return to the MOSCH lab 4-weeks after they receive the replacement hearing aids, a common time frame for patients to try out new hearing aids. We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). We will check the hearing aids and verify their function by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of the hearing aid in response to sound (beeps, noises, and/or speech). You will complete the hearing-aid questionnaires again to determine if you are happy with your new hearing aids (e.g., Client-Oriented Scale of Improvement, Abbreviated Profile of Hearing Aid Benefit, International Outcome Inventory for Hearing aids, and Satisfaction with Amplification in Daily Life). We also will provide an "exit interview" to ask you questions about your experimental hearing-aid fitting approach. If you experienced hearing-aid problems, then those will be addressed at the end of this

visit (e.g., programming changes, fit issues, etc.). It is estimated that this appointment will last 90-120 minutes.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. 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 withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, 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.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate. If you elect not to participate in this study, then you will receive your new hearing aids through the VA audiology clinic just like you normally would.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

The overall length of the study is 6-8 weeks.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

<u>The possible risks and/or discomforts</u> of your involvement include:

All of the procedures in this study are part of standard clinical practice, including the simulated hearing-aid fitting measurements (commonly used to fit hearing aids in infants and children who cannot tolerate a probe tube in their ear during real-ear measurements). The procedures are safe and pose less than minimal risk of harm or physical discomfort. There is a rare but known risk of ear injury from taking earmold impressions of your ears that are needed to make the custom-fit earmolds. We will follow careful clinical procedures to avoid ear injuries during earmold impressions. You may get tired or frustrated by listening to speech in noise and from completing questionnaires. Breaks can be provided if needed. You may have slight ear discomfort during probe microphone measurements. These measurements are routine and take only a few minutes to complete. If you feel any discomfort during any procedure at any time, then let us know. We can readjust the probe to be more comfortable in your ear or we will stop the test.

You may not like getting your hearing aids in the mail and would have preferred a face-to-face fitting. If you do not want to get your new hearing aids in the mail, then you do not have to participate in the study. Also, if hearing-aid problems arise, then you will have to wait until your next study visit to have them addressed by the research team should those problems not be addressed during the phone call. In the event that you cannot wear your new hearing aids, then you can go back to wearing your old

hearing aids until your next study visit. If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. All participants will receive a comprehensive hearing test and close follow-up with their hearing aids and these results will be reported in your VA medical record. In addition, you may enjoy the benefit of obtaining new hearing aids without having to come to the clinic for a fitting appointment. If we show that the experimental hearing-aid fitting approach is as good or better than the standard fitting approach, then this approach can be offered to Veterans receiving new hearing aids in the future.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be paid $50 for each face-to-face study visit. In this study, there are 2 face-to-face visits. Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

The study involves two face-to-face visits. After each visit, you will receive a direct deposit of $50 (if available) or be mailed a check for $50.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Smith may take you out of the study without your consent for one or more of the following reasons: (1) if she decides it is not in your best interest to continue (i.e., not following study related directions, adverse event), or (2) if the study ends early.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure

will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study. We will share the results of your hearing evaluation and your hearing aid fitting with you and record those results in your VA medical record. If we discover an issue for which we believe you need medical attention, we will refer you to your primary care doctor or other specialist as needed.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Research study data will not be shared.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded through a grant by the Department of Veterans Affairs Rehabilitation and Research Service (RR&D). The study audiologist and study coordinator receive salary from the VA RR&D grant. The Principal Investigator has a 3/8th VA appointment and receives a 3/8^{ths} salary from the Durham VA Medical Center.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

All paper records will be temporary stored in a locked cabinet (only accessible by the study staff) in a lockable office at the Duke lab. When you are done with the study, those paper records will be securely transported (using a locked container) by a study staff member to the Durham VA Medical Center for long-term storage in the VA Audiology Clinic (Building 1, Room D3018). Again, they will be stored in a locked cabinet in a lockable office with only the study staff having accessibility to your paper records.

For your electronic data, your private information (e.g., file with your name and last four of your social security number with your study ID) will be stored ONLY on the VA file in a secure VA folder on a VA server. Your hearing-aid serial numbers and the hearing aid settings will be stored on the Duke lab computer, but your file will be saved using your study ID and not your name. The coded data file (e.g., the file with your study ID, hearing test results, hearing aid information, and other study data) will be stored at the VA and also a copy on a Duke server. Coded data, such as but not to be limited to, Survey and Questionnaire responses, will be stored on the VA REDCap database. Again, only the

study staff members will have access to the electronic files. Your research records will be maintained and destroyed according to VHA records retention requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff and Duke University staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We may also disclose your information to VA RR&D. Your coded data (data with your Study ID and not your name) will be securely (e.g., encrypted method) sent to Dr. Todd Ricketts, a co-investigator on the grant who works at Vanderbilt University, and a statistician at Duke University, who will help with data analysis. We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH 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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Jamie Riedell at (919) 475-0101 during the day. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 1)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**

Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 2)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is:

When individuals are fitted with new hearing aids, the function of the hearing aids in the listener's real ear is tested using specialized equipment (procedure called real-ear verification), requiring the patient to be present at the fitting. The purpose of this study is to develop correction factors by measuring your ear acoustics with several hearing aid fittings. This will enable us to include those correction factors in an experimental hearing-aid fitting approach that would simulate the real ear of a person and thus allow us to fit the hearing aids to a person when they are not present in the clinic.

You are being asked to participate in this research study because you are a Veterans with hearing loss. In this study, we will recruit participants until we have data from 106 ears.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental portion of this study focuses on making measurements of several different hearing aids in a large sample of ears.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study, then you will have one face-to-face visit lasting about 90 minutes completed at the MOSCH Lab at Hock Plaza at 2424 Erwin Road, Suite 103, Durham, NC 27705. Even though this is a VA study, the data collection will occur at this Duke lab.

We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). All participants may receive have a standard hearing test if one was not completed at the VA in the last 6 months. We will test your middle ear function by placing a rubber probe tip in your ear canal. You will feel pressure and may hear loud beeping. You will wear earphones and listen for soft beeping sounds. You also may repeat words in quiet and noise. We will make sound measurements of your ear acoustics using a small probe tube in your ear canal along with a foam tip. We will make a measurement of your outer ear size with a measuring tool (similar to a ruler). We will fit 12 stock hearing aids on one of your ears by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of

the hearing aid in response to sound (beeps, noises, and/or speech). After each fitting, which will take a few minutes each, we will make a measurement of the hearing-aid output in our test box while you relax. We will continue fitting and testing the stock hearing aids until all 12 are fitted and all measurements made. This visit will last about 90 Minutes.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. 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 withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, 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.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate. There are no other options if you do not want to participate in this study. You would receive any needed VA Audiology services from the Durham VA Medical Center just like you normally would.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

The overall length of the study is one session lasting ~90 minutes.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

The possible risks and/or discomforts of your involvement include:

All of the procedures in this study are part of standard clinical practice. The procedures are safe and pose less than minimal risk of harm or physical discomfort. You may get tired or frustrated by listening to speech during the fittings, but breaks will be provided in between each fitting. You may have slight ear discomfort during probe microphone measurements, but these measurements are routine and take only a few minutes to complete. If you feel any discomfort during any procedure at any time, then let us know. We can readjust the probe tube or stop the test. You may get bored during each break. You may bring a book or other entertainment option to the visit for the breaks.

If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. Some participants will receive a comprehensive hearing test and these results will be recorded in your VA medical record. The data that we collect from the fittings in your ears will help us develop correction factors to include in our experimental hearing-aid fitting approach in the future. If that is successful, then we will be able to fit hearing aids in a "test box" and simulate the real ear of a patient. This approach would allow a Veteran to obtain replacement hearing aids and avoid a face-to-face visit. This may be beneficial for Veterans who have difficulty coming to the VA for their care.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be paid $50 the study visit. Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

The study involves one face-to-face visit. After the visit, you will receive a direct deposit of $50 (if available) or be mailed a check for $50.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Smith may take you out of the study without your consent for one or more of the following reasons: (1) if she decides it is not in your best interest to continue (i.e., not following study related directions, adverse event), or (2) if the study ends early.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study. We will share the results of your hearing evaluation and your hearing aid fitting with you and record those results in your VA medical record. If we discover an issue for which we believe you need medical attention, we will refer you to your primary care doctor or other specialist as needed.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Research study data will not be shared.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded through a grant by the Department of Veterans Affairs Rehabilitation and Research Service (RR&D). The study audiologist and study coordinator receive salary from the VA RR&D grant. The Principal Investigator has a 3/8th VA appointment and receives a 3/8^{ths} salary from the Durham VA Medical Center.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

All paper records (including this consent document, if you are consented at the Duke lab and coded study forms) will be temporary stored in a locked cabinet (only accessible by the study staff) in a lockable office at the Duke lab. When you are done with the study, those paper records will be securely transported (using a locked container) by a study staff member to the Durham VA Medical Center for long-term storage in the VA Audiology Clinic (Building 1, Room D3018). Again, they will be stored in a locked cabinet in a lockable office with only the study staff having accessibility to your paper records.

For your electronic data, your private information (e.g., file with your name and last four of your social security number with your study ID) will be stored ONLY on the VA file in a secure VA folder on a VA server. The coded data file (e.g., the file with your study ID, hearing test results, hearing aid information, and other study data) will be stored at the VA and also a copy on a Duke server. Again, only the study staff members will have access to the electronic files. Your research records will be maintained and destroyed according to VHA records retention requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff and Duke University staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We may also disclose your information to VA RR&D. Your coded data (data with your Study ID and not your name) will be securely (e.g., encrypted method) sent to Dr. Todd Ricketts, a co-investigator on the grant who works at Vanderbilt University, and a statistician at Duke University, who will help with data analysis. We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH 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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Jamie Riedell at (919) 475-0101 during the day. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 2)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**

Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 3)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is:

When individuals are fitted with new hearing aids, the function of the hearing aids in the listener's real ear is tested using specialized equipment (procedure called real-ear verification), requiring the patient to be present at the fitting. The purpose of this study is to determine if a simulated hearing-aid fitting approach (simulated real-ear verification) that does not require a visit is as good as the standard face-to-face hearing-aid fitting approach for experienced hearing-aid users getting new hearing aids.

You are being asked to participate in this research study because you are an experienced VA hearing aid user getting new (replacement) hearing aids that are the same style as your current hearing aids.

In this study, we will continue to recruit four groups of participants, until each contains 22 people. All groups will be receiving replacement mini behind-the-ear (BTE) hearing aids with either open or closed domes (the rubber tip at the end of the hearing aid tube that sits in the ear). Two groups will be the control group and receive the standard of care fitting approach and two groups will be receiving the experimental fitting approach. The assignment will be based on the type of dome you use (open or closed) and then you will randomly be assigned to the standard-of-care group or the experimental group, similar to drawing a number out of a hat.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental portion of this study focuses on the way in which the hearing aids are fitted (in a text box with you NOT present at a face-to-face visit) and sent to you (in the mail)—if you are randomly assigned to the experimental groups.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study, then you will have two to three face-to-face visits completed at the Audiology Clinic located at the MOSCH Lab at Hock Plaza at 2424 Erwin Road, Suite 103, Durham, NC 27705. Even though this is a VA study, the data collection will occur at this Duke lab.

Visit 1 (Face-to-Face). We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). All participants will have a standard hearing test. We will test your middle ear function by placing a rubber probe tip in your ear canal. You will feel pressure and may hear loud beeping. You will wear earphones and listen for soft beeping sounds. You also will repeat words in quiet and noise. We will make sound measurements of your ear acoustics using a small probe tube in your ear canal along with a foam tip. You will complete a memory like test to ensure you meet the study criteria. We will clean and maintain your current hearing aids. We will make measurements of your current hearing aids and ensure they are working properly and programmed to your latest hearing test. We will verify the hearing-aid function by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of the hearing aid in response to sound (beeps, noises, and/or speech). In addition, we will ask you several questions about your current hearing-aid knowledge to ensure that you can change your batteries, clean your hearing aids, etc. and ask you to demonstrate these skills. You will complete several hearing-aid outcome measures about your current hearing aids and their performance. You also will be asked how you would like your new hearing aids programmed. This visit is estimated to last ~120 minutes.

Visit 2. **For only those participants in the standard hearing-aid fitting approach group**, you will return to the Duke lab ~4 weeks after Visit 1 for a standard 30-minute hearing-aid fitting appointment. We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). Your earmolds and hearing aids will be fitted as usual. We will make real-ear measurements of your hearing aid function to ensure the best fit possible. We do this by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of the hearing aid in response to sound (beeps, noises, and/or speech). You will be given your manufacturer user manual and programming report from the hearing-aid software.

If you are assigned to the experimental hearing-aid fitting group, you will **NOT** come to the lab for your hearing-aid fitting. We will fit and program your hearing aids based on the measurements we made from you and your ears at Visit 1 as well as based on the several questions we asked you at Visit 1. We will verify the fit of your hearing aids in a "test box" that simulates your real ear acoustics. We will mail you your hearing aids along with your manufacturer user manual and programming report from the hearing-aid software.

All participants will be encouraged to wear their new hearing aids over a 4-week trial until they are seen for Visit 3.

Phone Call. All participants will receive a phone call approximately 2 days after the hearing aids are received in the mail. We will ask questions about the physical comfort of the hearing aids, sound

quality, and any other hearing-aid problems. We also will answer any questions you may have about your new hearing aids. This call will last < 10 minutes.

Visit 3 (Face-to-Face). All participants will return to the Duke lab 4-weeks after they receive the replacement hearing aids, a common time frame for patients to try out new hearing aids. We will examine your ears with an ear light. If wax is present, then you will be referred to the VA audiology clinic for an ear cleaning (not part of the research). We will check the hearing aids and verify their function by placing a small probe tube in your ear canal along with your hearing aid and measuring the output of the hearing aid in response to sound (beeps, noises, and/or speech). You will complete the hearing-aid questionnaires again to determine if you are happy with your new hearing aids (e.g., Client-Oriented Scale of Improvement, Abbreviated Profile of Hearing Aid Benefit, International Outcome Inventory for Hearing aids, and Satisfaction with Amplification in Daily Life). We also will provide an "exit interview" to ask you questions about your experimental hearing-aid fitting approach. If you experienced hearing-aid problems, then those will be addressed at the end of this visit (e.g., programming changes, fit issues, etc.). It is estimated that this appointment will last 90-120 minutes.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. 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 withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, 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.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate. If you elect not to participate in this study, then you will receive your new hearing aids through the VA audiology clinic just like you normally would.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

The overall length of the study is 6-8 weeks. You will have two to three face-to-face visits (depending on which group you are in) that will last 30-120 minutes each (depending on which study visit).

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

The possible risks and/or discomforts of your involvement include:

All of the procedures in this study are part of standard clinical practice, including the simulated hearing-aid fitting measurements (commonly used to fit hearing aids in infants and children who

cannot tolerate a probe tube in their ear during real-ear measurements). The procedures are safe and pose less than minimal risk of harm or physical discomfort. You may get tired or frustrated by listening to speech in noise and from completing questionnaires. Breaks can be provided if needed. You may have slight ear discomfort during probe microphone measurements. These measurements are routine and take only a few minutes to complete. If you feel any discomfort during any procedure at any time, then let us know. We can readjust the probe to be more comfortable in your ear or we will stop the test.

You may not like getting your hearing aids in the mail and would have preferred a face-to-face fitting. If you do not want to get your new hearing aids in the mail, then you do not have to participate in the study. Also, if hearing-aid problems arise, then you will have to wait until your next study visit to have them addressed by the research team should those problems not be addressed during the phone call. In the event that you cannot wear your new hearing aids, then you can go back to wearing your old hearing aids until your next study visit. If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. All participants will receive a comprehensive hearing test and close follow-up with their hearing aids and these results will be reported in your VA medical record. In addition, you may enjoy the benefit of obtaining new hearing aids without having to come to the clinic for a fitting appointment. If we show that the experimental hearing-aid fitting approach is as good or better than the standard fitting approach, then this approach can be offered to Veterans receiving new hearing aids in the future.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be paid $50 for each face-to-face study visit. In this study, there are 2-3 face-to-face visits depending on your group assignment. Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

The study involves two to three face-to-face visits depending on which group you are in. After each visit, you will receive a direct deposit of $50 (if available) or be mailed a check for $50.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Smith may take you out of the study without your consent for one or more of the following reasons: (1) if she decides it is not in your best interest to continue (i.e., not following study related directions, adverse event), or (2) if the study ends early.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study. We will share the results of your hearing evaluation and your hearing aid fitting with you and record those results in your VA medical record. If we discover an issue for which we believe you need medical attention, we will refer you to your primary care doctor or other specialist as needed.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Research study data will not be shared.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded through a grant by the Department of Veterans Affairs Rehabilitation and Research Service (RR&D). The study audiologist and study coordinator receive salary from the VA RR&D grant. The Principal Investigator has a 3/8th VA appointment and receives a 3/8^{ths} salary from the Durham VA Medical Center.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

All paper records (including this consent document, if you are consented at the Duke lab and coded study forms) will be temporary stored in a locked cabinet (only accessible by the study staff) in a lockable office at the Duke lab. When you are done with the study, those paper records will be securely transported (using a locked container) by a study staff member to the Durham VA Medical Center for long-term storage in the VA Audiology Clinic (Building 1, Room D3018). Again, they will be stored in a locked cabinet in a lockable office with only the study staff having accessibility to your paper records.

For your electronic data, your private information (e.g., file with your name and last four of your social security number with your study ID) will be stored ONLY on the VA file in a secure VA folder on a VA server. Your hearing-aid serial numbers and the hearing aid settings will be stored on the Duke lab computer, but your file will be saved using your study ID and not your name. The coded data file (e.g., the file with your study ID, hearing test results, hearing aid information, and other study data) will be stored at the VA and also a copy on a Duke server. Coded data, such as, but not to be limited to, Survey and Questionnaire responses, will be stored on the VA REDCap database. Again, only the study staff members will have access to the electronic files. Your research records will be maintained and destroyed according to VHA records retention requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff and Duke University staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We may also disclose your information to VA RR&D. Your coded data (data with your Study ID and not your name) will be securely (e.g., encrypted method) sent to Dr. Todd Ricketts, a co-investigator on the grant who works at Vanderbilt University, and a statistician at Duke University, who will help with data analysis. We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

Participant Name:	**Date:**
Study Title: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids (Study 3)	
Principal Investigator: Sherri L. Smith, Au.D., Ph.D.	**VAMC**: Durham

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH 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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Jamie Riedell at (919) 475-0101, during the day. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**