Duke University Health System

Consent to Participate in a Research Study ADULT
Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related hearing loss

CONCISE SUMMARY

We are doing this study to learn if wearing two hearing-aids is better than wearing one in people with hearing loss in both ears. Phonak® **Audéo**™ Paradise or Lumity hearing aids will be used in this study.

If you choose to join this study, you will:

- Be in the study for about 7 months
- Have a hearing test and a hearing aid fitting.
- Be randomly assigned (like the flip of a coin) to one of two groups:
  - Group 1 will use one hearing aid
  - Group 2 will use two hearing aids in the study You

  have an equal chance of being in either group.
- Once you have bought the hearing aid(s) and worn them for 3 months, you will have the chance to:
  - Add a hearing aid (if you were in Group 1) or
  - Return the hearing aid(s) if you prefer (at 3 months and again at 6 months).
- Fill out several surveys at three time points.
- Answer questions on a smartphone several times per day at two time points.
- You may be asked to participate in a one-time focus group discussion about your hearing aid experience.

We will pay you up to $225 for being in the study.

Possible risks include:

- Difficulty completing hearing tests
- Feeling uncomfortable answering the survey questions.

There is a possible risk of delay of the use of two hearing aids if you are put into the Group 1.

As part of this study, you will have a longer hearing aid trial period (6 months) and a discount in the price of the hearing aid(s).

If you are interested in participating, please speak with a member of the study team.

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Introduction
We are asking you to take part in this research study because you have hearing loss. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision.

As your study audiologist or study staff reviews this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.
Please tell the study audiologist or study staff if you are taking part in another research study.

A grant from the Patient-Centered Outcomes Research Institute (PCORI) will sponsor this study.
Portions of Dr. Sherri Smith's and her research team's salaries will be paid by this grant. PCORI was created to fund research that can help patients and those who care for them to make better informed decisions about the healthcare choices they face every day.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Sherri Smith, AuD, PhD will be your audiologist for the study for your research visits and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards as needed.

WHY IS THIS STUDY BEING DONE?
We are doing this study to compare the benefit of one or two hearing-aid fittings in people with hearing loss. Phonak® Audéo™ Paradise and Lumity hearing aid models will be used in this study.

Although currently most people are fitted with 2 hearing aids, there are data that suggests that using one hearing aid may be just as good as using two for some people. If so, this would save avoidable costs for some people.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 350 people will take part in this study at two different hospitals and medical facilities (about 300 people will take part at Duke and 50 at Vanderbilt).

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WHAT HAPPENS WHILE I AM IN THE STUDY?
If you choose to join this study, you will be asked to sign and date this consent form. You may have given us your email address so that the link to the online document could be sent to you, and so that a copy of it can be emailed to you.
We will make sure you are eligible for the study.

- You must have mild to moderate symmetrical hearing loss
- You must have had a hearing test within the last 6 months
- You must be willing to receive one or two hearing aids
- You must not have prior hearing aid experience longer than 3 months
- You must be willing to purchase the study-specific hearing aid(s)
- You must have access to a smart phone and the internet
- You must be able to read and understand English

Activities	**Baseline Visit**	**Visit Around Weeks 1-2**	**Around Weeks 10-11**	**3 Months**	**Around Weeks 22-23**	**6 Months**
Hearing Test (clinic)	**X**			**X**		
Surveys (in person or online)	**X**			**X**		**X**
Randomization to Group 1 or Group 2	**X**					
Sign Purchase Agreement	**X**					
Pay for the Hearing Aid(s)		**X**				
Fitting		**X**				
Learn Use and Care of Hearing Aid(s)		**X**				
Surveys (on your phone)			**X**		**X**	
Option to change hearing aid set-up (from 1 to 2 or 2 to 1 or a different setup altogether)				**X**		**X**
Focus Group (optional) [1]				**see comment below**		

[1] **Invitation to participate in a focus group will occur sometime after the 3-month study visit, and potentially after the 6-month study visit, depending on the timing of when the focus group occurs**.

Each visit is described in detail on the next page.

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Baseline Visit (Research Visit):

- You will fill out several surveys.
- You will have a hearing test.
- You will be told about the study hearing aids and how much they cost.
- You will have measurements of your ear taken to see what you need for your hearing aid(s).
- You will be randomly assigned (like the flip of a coin) to one of two groups.
    - Group 1 will use one hearing aid
    - Group 2 will use two hearing aids in the study
- You have an equal chance of being in either group.
- If you are randomized to one hearing aid, you will choose the ear you want fitted. If you do not have a preference, then you will be assigned the ear in which the hearing aid will be fitted.
- The study hearing aid(s) will be ordered from Phonak.

Around Week 1-2 (Standard Clinical Hearing Aid Fitting Visit):

- You will have a standard hearing-aid fitting.
- You will pay for the hearing aid(s) and the fitting at this time just as you would for a standard hearing aid purchase.
    - You will receive a discounted price on the study hearing aids because you are in this study. Please see the information under **Costs of the Hearing Aids** portion of the consent form for details about the discounted price and your payment.
- We will make sure the hearing aids are programmed to your hearing loss prescription.
    - To do this, we will place a small tube in your ear along with the hearing aid(s).
    - We will record what sound is coming out of the hearing aid in your ear when we play speech sounds at different volume levels (soft, medium, loud) and make sure no sounds are uncomfortably loud to you.
- We will teach you about the use and care of the hearing aids.
- Your 6-month (180 days) hearing aid trial period begins.

Around Week 10-11 (Research Visit):

- During the final weeks of the 3-month trial period, you will answer questions on your smartphone several times during the day.
    - You will receive text messages during the day that will prompt you to fill out a short survey. This will help us understand how you are hearing "in the moment."
    - The questions will be about **TV listening, small conversations in quiet, conversation in noise, and group conversation** and two listening conditions that you tell us that are important for you.
- The study coordinator will contact you to remind you to complete the survey, either by phone or email.

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- They will also ask you if you want to stay with your current hearing aid set-up (either 1 or 2) or change your hearing aid set-up at your 3-month research visit (either 0, 1 or 2 hearing aids), and tell you about any extra costs.

Month 3 Visit (Research Visit):

- You will be asked to fill out several surveys.
- Hearing tests with the research audiologist (with or without your hearing aid(s)).
- You will have the chance to
    - Buy an additional hearing aid if you were randomized Group 1, or to
    - Decide on a different hearing aid setup (we will tell you about any extra costs).
    - Return one or both hearing aids for a full refund of the device(s). You will also be refunded a portion of the fitting fee (minus the part that is non-refundable).

Focus Groups (Research Visit):

- You may be asked to participate in a focus group to understand your experience.
- Invitation to participate in a focus group will occur sometime after the 3-month study visit, and potentially after the 6-month study visit, depending on the timing of when the focus group occurs.
- The focus group will include 6-10 people who participated in this study.
- The focus group will be scheduled for 90 minutes and will be recorded.
- Reminders will be sent two weeks, 1 week and 1 day prior to the scheduled group via email, phone or text.

Around Weeks 22-23 (Research Visit):

- During the final weeks of the 6-month trial period, we will ask you to once again answer questions on a smartphone several times during the day. You will receive text messages during the day that will prompt you to complete a short survey.
    - The questions will be about **TV listening, small conversations in quiet, conversation in noise, and group conversation** and two listening conditions that you tell us that are important for you. The study coordinator will send an email or call to remind you about the EMA survey.
- The study coordinator will also ask you if you want to stay with your current hearing aid set-up or if you want to make a final change by adding one hearing aid or returning both devices. They will tell you about the additional cost if you decide to purchase a second hearing aid device.

Month 6 Visit (Research Visit):

- You will fill out several surveys that will take about 30 minutes to finish.
    - You will be sent an email link so you can do the surveys online from home.
- A study coordinator will remind you about completing the surveys during the week 22 email/phone conversation described above.

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HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for about 7 months. It's possible you may be contacted after your 6-month study visit about interest in participating in a one-time focus group discussion about your hearing aid experience. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study audiologist first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. Standard clinic activities would be to fit most people with symmetric hearing loss with two hearing aids and then return one if they only wanted one. Therefore, a possible risk may be the delay in using two hearing aids if you are randomized to Group 1.

There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Some of the hearing tests may be difficult because they are in background noise or ask you to remember numbers or speech. We can take a break during the hearing tests at any time.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

By providing your email address for use in the consent process, you are at risk for a loss of confidentiality because email is not a secure means of communication.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to join this study, there may be direct benefit to you. You will have a longer trial period using the hearing aids to decide if they work for you. You also have the chance to change your hearing aid set-up after three months (from 1 to 2, or from 2 to 1) and/or at 6 months.

We hope that in the future the information learned from this study will help other people with mild to moderate hearing loss.

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WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you can choose not to use hearing aids, use these same hearing aids or other types of hearing aids as part of your standard care; however, the discount price is only offered as a part of this study. Please talk to your audiologist about these and other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be seen by people involved in this research and may be seen by people collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Because (e-mail/text/etc.) does not provide a completely secure and confidential means of communication, please do not use e-mail and text if you wish to keep your communication private. Instead, contact the study coordinator. (Alternately, "please let us know and we will communicate with you only through regular channels like the telephone").

Office phone: (919) 684-6484
Email: eliza.sorrell@duke.edu

As part of the study, results of your study-related tests or procedures may be reported to PCORI and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations.
Reviewers may include representatives and affiliates of PCORI, the Duke University Health System Institutional Review Board, the Duke Surgery Office of Clinical Research, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests or procedures performed. Some of these procedures would have been done as part of your regular care. The study audiologist will use these test results both to treat you and to complete this research.

These test results will be recorded in your medical record and will be reported to the representatives and affiliates of PCORI. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

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The study results will be kept in your research record for at least six years after the study is finished. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept forever.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private.

If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study.

Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it.

The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with the study audiologist or a study team member**.**

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At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study sponsor, PCORI, has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

Costs of the Hearing Aids

Depending on whether you are randomized to Group 1 or 2 (1 or 2 hearing aids), you must purchase them to be in this study, just like you would if you were not in this study. Phonak® is offering the hearing aid(s) for this study at a lower price due to your participation in this study. The purchase amounts will vary depending on the specific hearing aid model you choose. You will be provided with an information sheet that includes the price information and a description of the different hearing aid models available as part of the study. We encourage you to talk to your audiologist to determine which model is best for you.
In addition to the cost of the hearing aids, there is also a fitting fee. Payment for the hearing aid(s) and fitting fee will be due at the time of fitting. Below is a range of costs for each study arm:

	1 hearing aid	**2 hearing aids**
Hearing Aid	$609 - $889	$1218 - $1778
Fitting Fee	$900	$ 900
Total Cost*	$1509 - 1789	$2118 - 2678

(*due at the time of fitting)

Please note that if you are randomized to Group 2 (two hearing aids), you will be paying more for hearing aids than you would if you chose to only buy one as part of your regular care. If you decide to return the hearing aid(s) at any point in the study, whether you are randomized to one or two hearing aids, you will get a refund of the purchase price of the hearing aid(s). If you return all hearing aid(s) you also will be refunded the fitting fee (minus $400 which is non-refundable).

Please read the Purchase Agreement carefully before deciding to participate in this study. You have 180 days (about 6 months) from the date of purchase to return the hearing aids and receive the refund. The study team will tell you how to return them.

We will monitor your DUHS patient care charges to make sure that costs are directed correctly. If you have any questions or concerns about billing, contact your study team coordinator so that he/she can help find a resolution.

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WHAT ABOUT COMPENSATION?
You will be paid up to $225 for your expenses related to your participation (parking, gas, and time) including

- $50 at each of the baseline and 3-month visits,
- $25 at each of the week 10-11, week 22-23, and month 6 visits, and
- $50 if you participate in the focus group.
- You will also receive parking passes, if applicable.

The collection of your social security number by the Duke study team is required in order to set up payment

Payment you receive as compensation for participation in research is considered taxable income. If you are paid more than $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). If you are paid more than $600 during any calendar year, Duke will send a 1099 (Miscellaneous Income) form to you and the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Sherri Smith at 919-613-1110 during regular business hours, and at 919-684-8111 (ask to have her paged) after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study.

If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Smith in writing and let her know that you are withdrawing from the study. Her e-mail address is sherri.smith@duke.edu, and her mailing address is DUMC 3887, Durham, NC 27710.

If you choose to withdraw from the study and do not want the hearing aid(s), you can return one or both for the refund described in the ***Costs of the Hearing Aids*** section of this consent form and in your Purchase Agreement.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your study audiologist may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study audiologist determines that it is no longer in your best interest to continue.

The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include loss of funding, non-compliance, or lack of recruitment. If this occurs, you will be notified and your study audiologist will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Sherri Smith at 919-613-1110 during regular business hours, and at 919-684-8111 (ask to have her paged) after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time