INFORMED CONSENT DOCUMENT

Project Title: **Barriers and Facilitators of Over-the-Counter Hearing Aids Success: A Patient Journey Approach**

Principal Investigator: Todd Ricketts, Ph.D.
Research Team Contact: Kjersten Branscome, Au.D., (319) 335-2631, ui-vu-hear@uiowa.edu

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult who is proficient in English, has a self-perceived mild-to-moderate hearing loss, and are intending to purchase a hearing aid in the next 6 months..

The purpose of this research study is to understand the decision-making process that people seeking a hearing aid go through when choosing between the traditional audiologist-fitted (prescription) hearing care pathway and an over-the-counter (OTC) pathway. There are two types of hearing aids available in the US—prescription hearing aids and over the counter (OTC) hearing aids. Prescription aids are those selected and fit with the help of a hearing healthcare professional. OTC hearing aids can be purchased directly and fit independently by the consumer. Additionally, this project seeks to characterize outcomes with these hearing aids over the first year of use.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 180 people will take part in this study conducted by investigators at the University of Iowa. Approximately 180 people will take part in this study conducted by investigators at Vanderbilt University Medical Center.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately one year.
The study requires 6 research sessions, while in-person visits are preferred, remote visits over Zoom and completing questionnaires from home are an option. The first two research sessions are approximately 2 weeks apart, the remaining 3 research sessions take place at 1-, 6-, and 12-months post hearing aid fitting. Each session has activities or questionnaires that will take 1 to 2 hours to complete.

A subset of participants will be asked to take part in 30-minute-long interviews regarding the decision-making process of choosing between OTC and prescription hearing aids and/or your decision to discontinue using your device(s)**.**

WHAT WILL HAPPEN DURING THIS STUDY?

Study Session 1: Consent

After you agree to participate and sign the consent form, you will be presented with a list of websites to help you begin your hearing aid decision-making process. You will also fill-out a demographics questionnaire. You will then be asked to think about which pathway you would like to pursue for the next two weeks. So that we do not influence your decision, research team members will not supply you with information regarding the different ways of getting hearing aids, answer specific hearing/hearing aid related questions, or give recommendations. It will be your responsibility to research OTC and prescription hearing aids or to contact the clinic for more information on the pricing and process.

Study Session 2: Decision

You will be contacted approximately 2 weeks after you first consent to be in the research study. At that time you will report whether you have decided to pursue OTC or prescription hearing aids. If you have not made up your mind in that time, you will be given two more weeks. If you still have not made your decision after 4 weeks you can decide to withdraw from the study or choose to be contacted by the research team monthly for up to 6 months.

If you do not decide to purchase hearing aids during that 6-month time, we will ask you to fill out some questionnaires regarding your decision-making style and your self-perceived hearing difficulties. The first 20 participants who choose not to pursue hearing aids will be invited to an interview about your decision-making experience via zoom. For qualitative purposes, the interview will be recorded and then transcribed. When transcription is complete, the recording will be deleted. You may opt out of the interview if you do not wish to be recorded. If you choose not to purchase hearing aids, you participation will end after you finish the questionnaires.

Once you have made the decision about which hearing aids to get, we will have you fill out some questionnaires. The questionnaires will cover things like your perceived hearing difficulty, decision making styles, frugality, ability to use technology, optimism, and attitudes towards health care professionals. These questionnaires may be completed in person or remotely from home.

If you choose the OTC hearing aids, you will be sent a questionnaire to screen for any medical issues that could be causing the hearing issues.

If you choose the prescription hearing aids, you may obtain your hearing aids from any licensed hearing aid dispenser, but the Audiology Clinic at the Vanderbilt University Medical Center is the preferred clinic.

The first 20 participants to choose either type of hearing aid will be invited for an interview about your decision-making experience via zoom. For qualitative purposes, the interview will be recorded and then transcribed. When transcription is complete, the recording will be deleted. You may opt out of the interview if you do not wish to be recorded.

It is possible that one of the branches of the study may be much more popular than the other. To keep the number of participants with each type of hearing aid roughly equal should that occur, further participation in the study for those in the over-populated choice will be randomly selected to continue with the study. The participation of those not selected to participate long-term will conclude after an in-person study visit. The visit will include measures of your hearing, ability to understand speech in

background noise, cognition, dexterity and working memory. These measures will be described in more detail later in this section.

Study Session 3: Start of Hearing Aid Use
Long-term participants will be encouraged to contact the research team once they have begun using their hearing aids. If we have not heard from you 6 weeks after you have made your decision, we will reach out to you to see if you have begun using your hearing aids. If you have not, we will follow-up again with you in 3 weeks. If at that point you have not begun using your hearing aids, you will have the choice of being contacted by the research team monthly for the next 4 months or withdrawing from the study. If you choose to keep participating and have not begun using your hearing aids by the end of the 4th monthly contact, you will be withdrawn from the study.

Study Session 4: 1-Month Post Start of Hearing Aid Use
Approximately 1-month after you begin using your hearing aids you will come to the research lab for an in-person visit. First, you will complete a hearing test. You will sit in a sound-treated room. Earphones will be placed in your ears and tones that vary in pitch and loudness will be presented through the earphones. You will be asked to press a button each time you hear a tone. Your ability to understand speech in noise will be assessed. Sentences and noise will be played from headphones. Your task to is repeat as many of the sentences as possible. Your dexterity will be measured by how quickly you can put pegs into a peg board with each of your hands.

We will do a cognitive screening by having you name, draw, repeat and memorize items. We will test your working memory by having you read groups of sentences and we'll ask you to try to remember as many of the first words or last words of each sentence in the group. Measurements of how the hearing aids are functioning in your ears will also be taken. You will complete a practical hearing aid skills and knowledge test where you will be quizzed on how to use and care for your device(s).

Lastly, you will fill out several questionnaires assessing self-perceived hearing difficulty, hearing aid satisfaction, hearing aid issues, hearing aid benefit, and hearing aid use.

Study Session 5: 6-Months Post Start of Hearing Aid Use
The research team will again follow up with you after you have been using your hearing aid(s) for six months. You will fill-out questionnaires assessing self-perceived hearing difficulty, hearing aid satisfaction, hearing aid issues, hearing aid benefit, hearing aid use and life events that may affect hearing aid use. If you participate in person, measurements of the hearing instruments in your ears will be taken. If you participate remotely, you will not undergo this measure.

Study Session 6: 12-Month Post Start of Hearing Aid Use
The research team will again follow up with you after you have been using your hearing aid(s) for one year. The procedures in this visit are identical to the Session 5 tasks.

Once all the study procedures are finished, your participation will be complete.

If you discontinue hearing aid use during the research study, the research team would like to interview you over Zoom about the reasons why. For qualitative purposes, the interview will be recorded and then transcribed. When transcription is complete, the recording will be deleted. You may opt out of the interview if you do not wish to be recorded.

Data Storage for Future Use

As part of this study, we are obtaining hearing and hearing aid data from you. We would like to study your hearing and hearing aid data in the future, after this study is over without further consent. Your sample, information, and/or data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

The tests we might want to use to study your hearing and hearing aid data may not even exist at this time. Therefore, we are asking for your permission to store your hearing and hearing aid data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding hearing aid success, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your hearing and hearing aid data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of hearing and hearing aid data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your hearing and hearing aid data will be stored *with a code which may be linked to* your age and gender. If you agree now to future use of your hearing and hearing aid data but decide in the future that you would like to have it removed from future research, you should contact **Yu-Hsiang Wu at (319) 335-2631.** However, if some research with your hearing and hearing aid data has already been completed, the information from that research may still be used.

WILL I BE NOTIFIED IF MY DATA RESULT IN AN UNEXPECTED FINDING?

We may learn things about you from the study activities which could be important to your hearing health. If this happens, you can decide whether you want this information to be provided to you. If you choose to have this shared, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your hearing threshold data. Your hearing tests may reveal an abnormality that is unrelated to the purpose of this research but that should be evaluated by an ear, nose, and throat doctor (otolaryngologist). If this happens, we will tell you about any such abnormalities. There may be benefits to learning about these incidental findings, such as early detection and treatment of a treatable cause of hearing loss. But there are also risks, such as suspecting a potentially curable cause of hearing loss, which on further testing turns out to be age-related or noise-exposure hearing loss. This is a risk because you or your insurance company will have to pay for this further testing. The research study will not cover the costs of any tests or consultations related to the evaluation of incidental findings.

The hearing test results will be reviewed by the research audiologist who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

However, if you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician. The study team/study will not cover the costs of any follow-up consultations or actions.

If you are interested in the results of this research study including your individual results, we can make them available to you after the study is completed. Please ask a member of the research team if you would like to see the results or if you have any questions about them.

Please initial one of the following options:

_____ Yes, I want to be provided with the results of my hearing test.
_____ No, I do NOT want to be provided with the results of my hearing test.

Audio and Video Recording

One aspect of this study involves making recordings of optional Zoom interviews regarding your decision-making process or discontinuation of hearing aid use with you. Zoom recordings are in audio/video format. The recordings will be stored on a secure server overseen by the University of Manchester. The interviews will be coded and transcribed within 30 days of the interview. Identifying information will not be included in the transcription. Upon completion of the transcription, the recordings will be deleted.

[ ] Yes [ ] No I wish to participate in the optional Zoom interviews.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may feel fatigue, frustration or boredom during the testing sessions. We will give you breaks between tests. Each visit will be no longer than two hours. It is likely that you may feel frustrated during tests in which there is background noise. It is normal to have difficulty recognizing soft speech in loud noise. There is also a risk of loss of confidentiality. Measures in place to protect confidentiality are noted in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the knowledge gained from this study may help us better understand the barriers and facilitators to hearing aid success in the OTC service pathway and the traditional hearing aid service pathway.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There is no cost to you for taking part in this study. However, there are costs associated with pursuing hearing aids. You will be responsible for purchasing the OTC or prescription hearing aid(s) of your choice.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. We may ask you for your Social Security number and address before you are compensated for taking part in this study. You will need to provide your social security number (SSN) in order for us to pay you when compensation is over $100. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $7.50 per half hour of study research. The total amount of research visit time will be between 5.5 and 7 hours for a total of $82.00 to $105.00. In addition you will be provided with vouchers to cover the cost of parking if you attend research sessions in person. You will also be compensated $0.20 for milage up to 100 miles round trip for in-person study visits.
If you decide to withdraw from the study, you will be paid for the non-intervention research time you have completed.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health/National Institute on Deafness and Communication Disorders (NIH/NIDCD) is funding this research study. This means that the University of Iowa is receiving payments from NIH/NIDCD to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH/NIDCD for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care.
There are no plans for Vanderbilt to give you money for the injury.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that we and *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure by storing it in a password protected computer in a locked office. You may request that your personal information be removed from this file at any time by contacting Yu-Hsiang Wu, M.D., Ph.D., (319) 335-9758 or uiowa-hal@uiowa.edu.

You may still participate in the research study even if you choose not to be in the registry.

[ ] Yes [ ] No I give you permission to put my name and personal information in a registry so that this research team and other researchers can contact me in the future about different research studies.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- the sponsor, NIH/NIDCD
- qualified researchers who request access to the registry
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will use only subject codes as identifiers on data sheets, secure all files in locked cabinets/rooms and use password-protected computer files. The list linking your study code and your name will be stored in a secure location that is accessible only to the investigators. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.
It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.
Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

Please contact the research team if you decide to drop out of the study. The research team can be reached at (319) 3352631 or ui-vi-hear@uiowa.edu.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because the arm of the study you are enrolled in, either OTC or prescription hearing aids, has many more participants than the other arm of the study. To keep the arms balanced your participation may be shortened and end just after you have made your decision on which type of hearing aids to get. Your participation may also be ended if you fail to decide to purchase hearing aids. See the "What will happen during the study?" section for more information on shortened participation.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Yu-Hsiang Wu at (319) 335-2631.** If you experience a research-related injury, please contact: **Yu-Hsiang Wu at (319) 335-2631.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)