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INFORMED CONSENT DOCUMENT

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

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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 interested in getting a hearing aid.

The purpose of this research study is understand the decision-making process that people seeking a hearing aid go through when choosing between the traditional audiologist-fitted hearing care pathway and an over-the-counter (OTC) pathway.

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 5 research visits, while in-person visits are preferred, remote visits over Zoom are an option. The first two visits are approximately 1 week apart, the remaining 3 visits take place at 1-, 6-, and 12-months post hearing aid fitting. Each visit will last 1 to 2 hours.

A subset of participants will be asked to take part in 30-minute-long interviews regarding your decision-making process**.**

WHAT WILL HAPPEN DURING THIS STUDY?

After you agree to participate and sign the consent form, you will be presented with brief information comparing the over-the-counter (OTC) hearing aid pathway and the traditional prescription hearing aid pathway (AUD). 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 week.

Visit 2 takes place approximately 1 week after the initial visit. At that visit you will report which pathway (OTC or AUD) you have decided to pursue. If you attend in-person, 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. Individuals who do not participate remotely will forego the hearing test.

Next, we will measure your personal characteristics that may impact hearing aid use. Your ability to understand speech in noise will be assessed. Speech and noise will be played from headphones plugged into a computer. You will hear a voice saying 3 numbers in a row. Your task to is repeat as many of the digits as possible. We will also assess your dexterity by having you rotate a quarter 180 degrees as many times as possible in 10 seconds with each hand.

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.

Lastly, you will fill out several questionnaires that assess your self-perceived hearing difficulty, your comfort with finding information on the internet, your decision-making style, and your attitude toward health care professionals.

If you choose the OTC pathway, you will be directed to a website to screen for any medical issues that could be causing the hearing issues: https://cedra-project.firebaseapp.com/#!/ You will also be directed to a website to help you choose an FDA registered OTC device that is right for you: https://www.hearingtracker.com/otc-hearing-aids?q=best+otc+hearing+aids. To participate in the study, you must choose a device that has been registered with the FDA.

If you choose the AUD pathway, you will be required to schedule your appointments at either the Audiology Clinic at the Vanderbilt University Medical Center or the Wendell Johnson Speech and Hearing Clinic at the University of Iowa.

You will receive no further instructions from the research team regarding your hearing aid journey. You will be required to let the research team know once you have received your hearing aid(s). The first 20 participants to choose either pathway will be interviewed about their 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.

Visit 3 takes place one month after you receive your hearing aids. 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). You will fill-out questionnaires assessing self-perceived hearing difficulty, hearing aid satisfaction, hearing aid issues, hearing aid benefit, hearing aid use and general quality of life. 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.

Visit 4 takes place after you have been using your hearing aid(s) for six months. The procedures in this visit are similar to the visit 3 tasks. You will fill-out questionnaires assessing self-perceived hearing difficulty, hearing aid satisfaction, hearing aid issues, hearing aid benefit, hearing aid use and general quality of life. 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.

Visit 5 takes place after you have been using your hearing aid(s) for one year. The procedures in this visit are similar to the visit 3 and 4 tasks. You will fill-out questionnaires assessing self-perceived hearing difficulty, hearing aid satisfaction, hearing aid issues, hearing aid benefit, hearing aid use and general quality of life. 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.

Once all of 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) 335-9758.** 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?

It will not cost you anything to be in this research study. However, there are costs associated with pursuing hearing aids. You will be responsible for purchasing the OTC or audiologist fit device(s) of your choice.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research 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 in the University Ramps.
If you decide to withdraw from the study, you will be paid for the non-intervention research time you have completed.

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.

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.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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 University of Iowa study team can be reached at (319) 335-9758 or uiowa-hal@uiowa.edu.

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) 335-9758.** If you experience a research-related injury, please contact: **Yu-Hsiang Wu at (319) 335-9758.**

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)