Official Title of the study: Longitudinal Outcomes of Hearing Aids

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INFORMED CONSENT DOCUMENT

Project Title: **Longitudinal Outcomes of Hearing Aids**

Principal Investigator: Yu-Hsiang Wu

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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 a native English speaker between the ages of 55 and 85 who has a hearing loss.

The purpose of this research study is to assess the long-term outcomes of over-the-counter (OTC) hearing aids with a study-provided smartphone survey app. This may provide information which will help to better inform consumers who are pursuing this line of hearing rehabilitation when these become available to the public.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 45 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 3 to 4 months. Your participation will include 7 visits to the research lab and a 12-week long hearing aid field trial. Each lab visit will last between 1.5 and 2.5 hours.

WHAT WILL HAPPEN DURING THIS STUDY?

Visit 1
If you consent to participate in this study, we will first assess your hearing. You will be given a hearing test during which you will be asked to respond to sounds through headphones. After the hearing

screening, if you are eligible to continue and are not tired, we will have you remain in the sound room and we will test your ability to understand speech in background noise. If you are tired, you will be given an opportunity to rest for a while. When you are ready to continue, speech and noise will play through loudspeakers in the room and you will repeat as much of it as you can.

Next, we will measure your personal characteristics that may impact hearing aid use. 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. Next you will fill-out 5 questionnaires assessing how you hear without amplification.

We will then train you on how to use our smartphone survey app. You will then practice with the survey app as go about your daily life for the next three days. You will return to the lab approximately 1 week later for the OTC hearing aid fitting visit. The visit should take no longer than 2.5 hours

Visit 2
At this visit you will select the model of OTC hearing aid you wish to use during the field trial. You will listen to simulated hearing aids through a computer program on a tablet and choose the amplification setting you like best for each ear. Because we are investigating OTC hearing aids, you will be responsible for teaching yourself how to use and care for the devices. You will be provided with written information as well as access to information and instructional videos via a website: ExactHearingCare.com. You will fill-out a questionnaire about your hearing aid expectations. We will re-train you on how to use our smartphone survey app. You will then go about your normal life for the next week completing smartphone surveys while you teach yourself how to use the hearing aids. Visit 2 should take no longer than 2 hours. You will return to the lab in approximately 1 week to return the smartphone to the lab and continue with lab testing.

Visit 3
During this visit measure what the hearing aids are doing in your ears and have you fill out more questionnaires. The questionnaires will assess your personality and your attitude toward hearing aids. We will also have you take a short health literacy test. Next, we will test your manual dexterity by having you put pegs into and remove them from a board with each of your hands. Visit 3 should last no longer than 2 hours. You will continue to use the hearing aids in your daily life for the next 4 weeks without doing any smartphone surveys. You will return to the lab in approximately 4 weeks. Visit 3 should last no more than 2 hours.

Visit 4
After you have been using the hearing aids for 5 weeks, you will return to the research lab. At this visit we will measure how the hearing aids are working in your ears and test your ability to understand speech in noise with the hearing aids. You will be re-trained on how to use our smartphone survey app. You will again be sent out to live your daily life while assessing how you hear with the hearing aids using our smartphone survey app for 1 week. You will return to the lab in approximately 1 week. Visit 4 should last no longer than 1.5 hours.

Visit 5
You will return to the lab in one week to return the smartphone. At this visit you will fill-out many paper

and pencil questionnaires about how you now hear while using the study hearing aids. This visit should last no longer than 1.5 hours. You will then use the hearing aids, without assessing them through smartphone surveys, for the next 5 weeks. You will return to the lab in approximately 5 weeks.

Visit 6
Visit 6 procedures will be identical to visit 4. After you have been using the hearing aids for 11 weeks, you will return to the research lab. At this visit we will measure how the hearing aids are working in your ears and test your ability to understand speech in noise with the hearing aids. You will be re-trained on how to use our smartphone survey app. You will again be sent out to live your daily life while assessing how you hear with the hearing aids using our smartphone survey app for 1 week. You will return to the lab for your final visit in approximately 1 week. Visit 6 should last no longer than 1.5 hours.

Visit 7
You will return to the lab in one week **to return the smartphone and hearing aids,** and complete the research study. At this visit you will fill-out many paper and pencil questionnaires about how you now hear while using the study hearing aids. We will also assess your knowledge and ability to use the hearing aids. We will also answer any questions you have about amplification. This visit should last no longer than 1.5 hours.

Data Storage for Future Use
As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the effectiveness of hearing aids, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Yu-Hsiang Wu, M.D., PhD, at 319-335-9758. However, if some research with your data has already been completed, the information from that research may still be used.

(Please place your initials next to your choice below)**:**

My data may be used for future research.

_____ Yes _____ No

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

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who

normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

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 during the testing sessions in the laboratory. We will give you breaks between tests. Each visit will be no longer than two and a half hours. It is also likely that you may feel frustrated in some laboratory test environments in which there is background noise. It is normal to have difficulty recognizing soft speech in loud noise. You may also feel frustrated from having no instruction on how to use the hearing aids. 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, others who are pursuing over-the-counter hearing aids might benefit from the knowledge we hope to gain from it.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

It will not cost you anything for being in this research study.

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 $100 or more. 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 in-person laboratory research time, and this excludes the time related to hearing aid intervention. The total amount of in-person laboratory research visit time will be approximately 10 to 14 hours depending on how quickly you complete the lab procedures. We expect total compensation to range between $150-$210. 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 in-person laboratory research time you have completed.

WHO IS FUNDING THIS STUDY?

The National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from NIDCD/NIH 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 NIDCD/NIH 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 or 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 on password protected computers 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.

You may still participate in the research study even if you choose not to be in the registry. (Please place your initials next to your choice below):

I give you permission to put my name and personal information in a registry so that other researchers can contact me in the future about different research studies.

_____ Yes _____ No

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 National Institute on Deafness and Other Communication Disorders (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 subject 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 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)