Official Title of the study: Hearing Aid and Individuals With Cognitive Disorders

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INFORMED CONSENT DOCUMENT
Research Partners

Project Title: **Impact of hearing aid intervention in individuals with mild and moderate major cognitive disorder**

Principal Investigator: Yu-Hsiang Wu

Research Team Contact: **Elizabeth Stangl, Au.D., Yu-Hsiang Wu, M.D., Ph.D., Dave Moser, Ph.D (319) 335-9758 or uiowa-hal@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 a native English-speaking adult between the ages of 55 and 85 who has a diagnosis of mild or moderate major neurocognitive disorder and has a hearing loss but no experience with hearing aids. You also have a caregiver willing to participate in the study.

The purpose of this research study is to investigate hearing aid outcomes in individuals with major cognitive disorder and their caregivers.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at the University of Iowa. Approximately 20 people will take part in the same study conducted by investigators at Vanderbilt University in Nashville, TN.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for
4 to 6 research visits lasting no longer than 2.5 hours each plus a 7 week-long hearing aid field trial. Length of participation should last approximately 2 months.

WHAT WILL HAPPEN DURING THIS STUDY?

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. 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, we will test your manual dexterity by having you put pegs into and remove them from a board with each of your hands. You will also complete a questionnaire assessing how you hear out in the real world. You will then be randomly assigned to one of the three intervention groups. All three groups will receive hearing aids and services from audiologist.

Group 1: This group will receive hearing aids and typical hearing aid fitting services.
Group 2: This group will receive hearing aids and typical hearing aid fitting services, but the hearing aids will provide less amplification compared with Group 1.
Group 3: This group will receive hearing aids as well as services. The services provided in this group are less comprehensive, but more efficient, than Group 1.

In one week, you and your caregiver will return for the second visit. Your hearing aid intervention will then begin. You will be provided with a pair of study hearing aids and you will fill out a questionnaire on how you expect the hearing aids will impact your life.

The next part of the study is a 7-week field trial with the study hearing aids.

After you have used the hearing aids for six weeks, we will have you and your caregiver return to the laboratory. At that visit we will take some measurements of the hearing aids' features while you wear them and test your ability to hear in noise with the hearing aids. You will wear your hearing aids for one more week after this visit.

After you have used your hearing aids for seven weeks, you and your caregiver will return to the laboratory to finish the study. At that research visit we will have you fill out more questionnaires based on how you heard with the study hearing aids. We will also test your ability to manipulate and use the hearing aids. We will end with interviewing you about your experience with the hearing aids and answering any questions you have about your hearing. The interview will be recorded, but you may opt out of it if you do not wish to be recorded. You will then be informed about which intervention group you have been assigned and your participation will be complete.

Your caregiver will also participate in the study. He/she will be asked to answer paper and pencil questionnaires based on how you hear, and how your hearing loss and hearing aid use affects your lives. Your caregiver will also answer smartphone surveys about how you hear in your daily life without hearing aids for one week before you begin using the study hearing aids. She/he will again answer smartphone surveys about how you hear with the study hearing aids during the last week of the study.

Data Storage for Future Use

As part of this study, we are obtaining hearing-related data from you. We would like to study your data in the future, after this study is over. Your 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 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 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 hearing loss and the effectiveness of hearing aid use in individuals with major cognitive disorder, 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 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-related 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 data will be stored *with a code which may be linked to your name and date of birth***.** 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 at (319) 335-9758. However, if some research with your data has already been completed, the information from that research may still be used.

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

The results from the cognitive 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.

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. There may be benefits to learning such results (such as early detection and treatment of hearing loss), but there are risks as well (such as feeling worried about a finding for which no treatment is available). We will test your hearing and the results may show that you have a hearing loss.

The hearing test results will be reviewed by an audiologist who normally reads such results and they will inform us if there are any unexpected findings. 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.

Please initial one of the following options:

_____ Yes, I want to be provided with this information.
_____ No, I do NOT want to be provided with this information.

Audio Recording

One aspect of this study involves making audio recordings of the final interview. The audio will be used to ensure that we do not miss any information you provide about your study experience. The recordings will be reviewed to obtain qualitative data about your hearing aid experience. The recordings will be made by a digital recorder in the Hearing Aid and Aging Research Lab.

The investigator and research team will use a password-protected computer to review the recording. If you don't want a (or parts of the) recording to be analyzed, the research team will not analyze it and the recording will be deleted permanently.

You may still be in the study if you do not wish to be audio recorded

[ ] Yes [ ] No I give you permission to make audio recordings of me during this study.

Communicate with your health care provider(s)

To ensure your safety throughout the study, we would like to communicate with your health care provider(s) about your participation in the study, such as sending a letter at the start and finish of the study. We may also contact your health care provider(s) during the study period, for example, if significant cognitive or mood changes are discovered. You will sign a release of information for any health care provider you would like us to communicate with.

[ ] Yes [ ] No I give you permission to communicate with my designated health care provider(s).

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. 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 the knowledge we hope to gain from it.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, you can discuss the other options that are available to you with your doctor. Instead of being in this study, you could choose to pursue hearing aids through an audiologist or hearing instrument specialist, or take no action.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any costs for being in this research study. The sponsor will cover the cost of the study hearing aids.

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 study research time, excluding time related to hearing aid intervention. The total amount of non-intervention research visit time will be approximately 7.5 hours, for a total of $112.50. In addition you will be provided with vouchers to cover the cost of parking in the University Ramps. You may also keep the study hearing aids at no cost if you choose. The study hearing aids are valued at $400.

If you decide to withdraw from the study you will be paid for the non-intervention research time you have completed and you will need to return the study hearing aids.

WHO IS FUNDING THIS STUDY?
The National Institute for Deafness and Other Communication Disorders (NIDCD), which is a branch of the National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from the 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 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 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.

[ ] Yes [ ] No 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.

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.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and our collaborating center at Vanderbilt University Medical Center.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be

given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Yu-Hsiang Wu, 250 Hawkins Dr., Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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.

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 of a change in your ability to consent. If your experience a decline in cognition, the researchers may end your participation because they are unable to determine whether you want to continue on with the research study.

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)