Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Auditory Brain Training to Enhance Satisfaction and Usage of New Hearing Aids by Older Adults

Principal Investigator: Craig Buchman, MD

Research Team Contact: Craig Buchman, MD(314) 362-7667

This consent form describes the research study and helps you decide if you want to participate. It 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 and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- 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.

This is a research study conducted by Craig Buchman, MD having to do with auditory training and new hearing aids. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant:

1. You will be fitted with two digital hearing aids free of charge. We will adjust the hearing aid so it is appropriate for your hearing abilities and challenges. You can keep these hearing aids at the end of the study. We will mail the hearing aids directly to you and then fit the aids and show you how they work via your computer and a Zoom call. Testing will be conducted via Zoom calls on your computer. Assessments will include speech perception measures and questionnaires and will occur on at least three occasions.
2. Once you receive your new hearing aids, we will ask to participate in a web-based hearing wellness program called Amptify. The purpose of Amptify is to help you get good benefit from your new hearing aids. Six days a week, you will use your iPhone, computer, or tablet to play listening games and learn new information about making the best of your hearing. You will also get support from a "listening coach."
3. The study lasts about 8 weeks. Once we give you the new hearing aids, you will spend four weeks engaged in the Amptify training activities and four weeks watching a TV program of your

choice. The time commitment for Amptify or television watching will be 6 days a week, each day for about 25 minutes.

4. A researcher will check in with you weekly via phone calls, emails, or through a chat function built into the Amptify online program. They will be available to answer any questions you might have.

You may benefit from volunteering because hearing aid use and auditory training are considered the primary rehabilitation approach for those with hearing loss. They have been shown to help others. This study will provide both for you.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have a hearing loss and have not worn hearing aids in the past. The purpose of this research study is to follow your progress as you participate in an online auditory training program after you begin wearing a hearing aid. We would also like your feedback about the auditory training system that you used. The auditory training system is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be fit with new hearing aids. Over the next two weeks we will fine-tune the fitting. We will need the results of your most recent hearing test to program your hearing aids. If available, we will get this information from your medical records or research records. If your testing was at an outside location, we will ask you to provide a copy of the report. If you are unable to provide a copy of your hearing test done within the last 12 months or you had a hearing test greater than 12 months ago, you will be invited to the medical center for a hearing test.

Once the hearing aid is deemed to be a good fit for you will be enrolled in an 8-week training program. Half of the training program will be eight hours of home-based online auditory training and the other half will include eight hours of independent closed caption TV watching at home. You will be asked at three four-week intervals to do more speech and hearing testing and respond to questionnaires about your performance and your opinions of the training methods. You will be free to skip any question that you prefer not to answer.

The final assessments will be four weeks after you have completed both the online training and the TV watching intervals. At the end of the study you will be allowed to keep the hearing aids but any maintenance, adjustments, or repairs will become your responsibility.

We will need to be in touch with you throughout your participation in the study to check on your hearing aid use, monitor progress with the training, and schedule your next visit. We will do this by emailing you, calling you, or video calling you through Zoom to ask questions every week. If you do not respond to emails in 24 hours, we will call you. If you are not able to be reached we will attempt to contact you through the alternative emails and phone numbers that you have provided. If you appear no longer able to participate in the study we will need to ask you to return the hearing aids.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding hearing loss, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data**.**

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Identifiers may be removed from your private information including data and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 35 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 15 weeks. The first few weeks involve hearing aid fitting and adjustments and the remainder of the time you will be asked to do approximately eight hours of auditory training from home and eight hours of independent closed caption TV watching at home. You will also be asked to respond to emails once each week reporting how much time you are training and how much time you are wearing your hearing aid.

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.

At WUSM, we do not routinely dispense a hearing aid without fitting them in the clinic as this is best practice. However, there are many direct to consumer hearing aid models and hearing aid dispensers across the US, who use the hearing aid fitting methods used in this study.

- Rarely hearing aids can amplify sounds into a rage that might be considered uncomfortable. They are designed with safety features to help avoid becoming dangerous or too uncomfortable. These features could fail or be incorrectly configured for your hearing loss. You should remove the hearing aid if you feel any sound is too loud.
- Rarely hearing aids cause an irritation or skin rash when worn for extended periods of time. You should remove the hearing aid if you feel a rash has occurred.
- The training activities require you to focus on the same tasks for extended periods of time, this may cause boredom or fatigue in some.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we have learned from your participation in the study.

WHAT OTHER OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. An alternative to the current study would be to contact your hearing healthcare professional (Audiologist, Speech-Language Pathologist, and/or Otolaryngologist) and follow a typical clinical rehabilitation protocol that would likely include a recommendation for hearing aids and auditory training.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will have no costs 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. 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. It may take up to four weeks to mail the check to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You could be paid up to $210:

- You will be paid $10 per hour, up to 8 hours for the online auditory training.
- You will be paid $10 per hour, up to 8 hours for the closed caption TV watching.
- You will be paid $10 for each online assessment, up to 5 assessments

You will be provided with a digital hearing aids to participate in the study. Once you have completed participation in the study, you will be allowed to keep the hearing aid.

DOES THE INVESTIGATOR OR OTHER RESEARCH TEAM MEMBER HAVE PERSONAL FINANCIAL INTEREST IN THIS STUDY?

Drs. Nancy Tye-Murray and Brent Spehar are part of the study team, Washington University employees and founders of a corporation that created the online auditory training system you will use in this study. The name of the company is Customized Learning Exercises for Aural Rehabilitation (clEAR). Washington University has financial interests potentially related to this study. clEAR and Washington University can potentially benefit financially from the outcome of this study.

WHO IS FUNDING THIS STUDY?

The National Institute for Deafness and Communication Disorders (NIDCD), an institute of the National Institutes of Health (NIH), is funding this research study. This means that the Washington University is receiving payments from 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.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

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.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration

- The National Institutes of Health (NIH) to complete funding source responsibilities if necessary
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, whenever possible we will use non-identifiable information when creating accounts for online services. We will use email for communication, if you prefer we can help create a non-identifiable Gmail address that you can use throughout the study. All research data provided to us will be kept in a secure place and will not be stored with any information that could be used to identify you. HIPAA compliant Zoom platform will be used during the hearing aid fitting and testing.

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

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- we will contact you to check on your hearing aid use, monitor progress with the training, and appointment scheduling containing PHI
- sending study information
- Consent documents
- Medical releases

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an

urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

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. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

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 withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study. If you decide to leave the study early, we will ask you to inform us and choose a time to return any equipment or technology that has been loaned to your during the study. These may include a hearing aid and the accessories for that hearing aid.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because it appears that you can no longer complete the strict timeline established for this study. As with all research studies, it is also possible that the funding for the research project will end before the study is complete.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Craig Buchman, MD at (314) 362-7667. If you feel that you have been harmed in any way by your participation in this study, please contact Craig Buchman, MD at (314) 362-7667.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form 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 agreeing to participate in this study.

As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

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 signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 09/13/21.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)