Washington University in St. Louis

FOR IRB USE ONLY
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EXPIRATION DATE: 12/01/20

INFORMED CONSENT DOCUMENT

Project Title: Customized auditory brain training for children with hearing loss. (Focus Group)

Principal Investigator: Craig Buchman

Research Team Contact: Elizabeth Mauze', (314) 747-7181

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

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 Dr. Craig Buchman having to participate in a focus group to talk about auditory training games. 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 have previously participated in this focus group with us (IRB ID #: 201602007), you can sign this form to allow us to use the data that was collected then for the current study.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend 1-2 hours in a focus group. You will need to come to a conference room at CID on the Washington University School of Medicine. During the focus group, you will be asked questions about another child who has hearing loss, about the training games that you played and questions about you and your hearing loss. The main risks to you if you participate are boredom or fatigue associated with sitting for a long period of time in a classroom.

We don't expect this study to benefit you directly, but it will help us understand the most effective and best methods for providing auditory training to those who need it. By volunteering you may help

someone else in the future. There is no cost to you and you will be paid $20 for participating in the focus group. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

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 use a hearing aid and are between the ages of 6 and 12 years of age.

If you have previously participated in a focus group with us (IRB ID #: 201602007), you can sign this form to allow us to use the data that was collected then for the current study.

The purpose of this research study is to determine the kinds of speech recognition training that most benefit children with hearing loss through the use of computerized listening games. Research has shown that poor speech recognition leads to poor academic achievement. This project offers a potential solution to this problem.

WHAT WILL HAPPEN DURING THIS STUDY?

You are being asked to participate in a focus group to talk about auditory training games. During the focus group, you will be asked questions about another child who has hearing loss, about the training games that you played and questions about you and your hearing loss. The focus group will be audio/videotaped so that your answers can be transcribed and analyzed. The audio/videotape may also be used for educational purpose (for example-at a professional conference or in an educational presentation). It will take about an hour and a half and will be at Washington University. You are free to skip any questions that you would prefer not to answer.

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

As part of this study, we are obtaining focus group data from you. We would like to use this data 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 speech perception in children with hearing loss. 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 for use of your data. 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 commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual 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.

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

Audio/Video Recording or Photographs

One aspect of this study involves making audio and video recordings during the focus groups. We will audio and video record the focus group discussions so that we can transcribed what was said and by who after the focus group is completed. Only the study team members will have access to the audio and video recordings. The audio and video recordings will be stored in a locked file cabinet and will be destroyed when the study is closed.

I give you permission to make audio and video recordings of me during this study.

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

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10 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 a 1.5 hour focus group.

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.

Risks may include boredom or fatigue. Other than that, there are no foreseeable risks and discomforts associated with this research.

Breach of Confidentiality
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 will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because others might benefit in the future in terms of the knowledge that will be gained.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid $20 for participating in the focus group. 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 will take approximately three weeks to receive your payment via the mail. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

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 Institutes of Health 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
- 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, we will code all information with a code that will not identify you. A master list linking the code and your identity will be kept separate from the research data. Only the PI and people helping him/her will be able to see the list. We will protect your information. If we write a report or article about the study, we will do it in a way that you will not be identified. 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. Sharing this information will allow 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 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 only contact you via email to schedule or cancel appointments or to answer questions that you may have.

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.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

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 results for items on the screening tests have changed since the initial screening or because you no longer wear hearing aids/cochlear implant or because there is no longer funding to support the study.

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WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Elizabeth Mauze at 314-747-7181. If you feel that you have been harmed in any way by your participation in this study, please contact : Elizabeth Mauze at 314-747-7181.

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: 12/01/20.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 12/01/20.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

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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)