PERSONAL SOUND AMPLIFICATION DEVICE STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN, INFORMED CONSENT FORM

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STUDY PROTOCOL

The proposed involvement of human subjects in this research includes transportation to and from the test site for a one-time appointment. Subjects will undergo audiologic testing procedures that are similar to those encountered during routine clinical audiologic care. The proposed procedures are no more than minimal risk for the subjects.

The inclusion criteria in this study are Primarily English-speaking adults who report difficulty hearing in some daily listening situations and can follow instructions and perform study procedures. Subjects will be excluded if they cannot follow the instructions and complete the speech perception testing questionnaires.

There will be no collaborating sites where human subjects research will be performed.

Study procedures, Materials, and Potential Risks

Subjects will attend to the behavioral tasks for approximately 1-1.5 hours with breaks provided as needed. The behavioral tasks require raising a hand when soft sounds of different pitches are detected, repeating pre-recorded sentences, and providing subjective feedback. The procedures will then be repeated with the subject wearing the PSAP with prescriptive gain sound output, and the PSAP with fine-tuned sound output.

The sources of research material obtained from living human subjects are names; dates (date of birth, date of testing, etc.); test results (speech perception scores, hearing thresholds, questionnaires); and non-sensitive general and otologic health information (i.e., HIV status, substance abuse, etc. will not be recorded). Upon enrollment, each subject will be assigned a number to which identifiers, test results, and health information will be linked. Only research personnel who are directly involved with this research will have access to individually identifiable private information about human subjects. All personnel are trained and approved by the designated institution to conduct human subject research. Behavioral data will be collected by the research personnel, and data collected from the medical records will be obtained according to the procedures for requesting records through the respective medical records departments. All data collected are specifically for the proposed research project.

Data will be recorded from subjects specifically for use in this study. The auditory data recorded includes: speech perception scores, behavioral thresholds, and subjective feedback questionnaires. In addition, a data from medical chart review for risk factors, hearing loss etiology, and general information will be obtained. Each subject will be assigned a code and all data will be maintained in a protected database identified only by that code. A single copy of a list with names, codes and contact information will be kept in a locked file cabinet in the locked laboratory space designated for Dr. Runge's Laboratory to protect identifying information.

This study is considered to have no more than minimal risk. Patients may become bored with the testing. The test equipment and procedures to be used have been used in previous studies with human subjects with no adverse effects. All of the equipment is used in clinical settings. Loss of confidentiality is a potential risk. Procedures are in place to minimize the potential risks to make loss of confidentiality less likely. A loss of confidentiality may be considered serious risk; however, sensitive health information is not collected as data for this research, and the data collected for this research is not anticipated to cause physical, psychological, financial, or legal difficulties for subjects and/or their families.

Informed Consent and Assent

Subject recruitment and enrollment will take place at Froedtert Hospital/Medical College of Wisconsin. Planned inclusion and enrollment for this study was primarily based on the existing 'Informatics for Integrating Biology and the Bedside' (i2b2) database system. I2b2 queries EPIC medical records of patients at Froedtert Hospital/Medical College of Wisconsin. The inclusion and enrollment plan for this study was accomplished by querying i2b2 for patients with diagnosis codes including sensorineural hearing loss (SNHL) and the demographic variables in relation to the condition prevalence. Also, since the inclusion criteria includes subjects that may not have a diagnosis of SNHL or related condition, we incorporated census data to reflect the general population in our region. One of the research personnel will contact the individual either in person,

by phone, or by email. Individuals who are not directly seen in the clinic will be contacted by research personnel by phone or email. The consenting process for study participation will be performed in person. During this time the research personnel will describe the study aims, procedures, risks, and benefits. The patient will be given ample time to read and consider the consent form, and the research personnel will encourage the patient to ask questions. It will be made clear to the patient that participation in this research has no bearing on the clinical care they receive. If the patient agrees to participate, he or she will sign the IRB-approved consent form, along with the designated research personnel.

Protections Against Risk

The potential risks will be minimized as much as possible. If evidence of adverse events is noted, the reasons for these events will be identified and rectified. To protect the subjects' confidentiality, records will be kept in a secure, locked room to which only authorized individuals have access, and any electronic records (e.g., databases, spreadsheets) will be kept on password-protected computers within the investigators' locked offices and laboratories. In addition, when data from the study are presented to the public the information will not be identifiable with any of the subjects. Any data shared between MCW, UWM, and Ascending Hearing Technologies, LLC, will be securely transmitted using the same protocols in place for clinical patients. In addition, we plan to develop a secure ftp site for sharing of data.

The measures proposed to protect subjects against risk are highly likely to be effective. At MCW, data will be collected in the same area as the Otolaryngology clinic during the hours of clinic operation, and in the event of an adverse effect during any research procedure, there will be many medical professionals within close proximity of the subject.

Potential Benefits of the Proposed Research to Research Participants and Others

The primary potential benefit of the proposed research is to society, and may ultimately help individuals have improved access to sounds. Subjects will not immediately benefit as the PSAD cannot be taken home, but the more research is performed in this area and product development advances, the more likely this information will benefit those who have difficulty hearing in some daily listening situations.

Importance of the Knowledge to be Gained

The knowledge gained from this study may ultimately help subjects hear better and may help those with hearing difficulties get access to sounds. The risk to subjects is minimal, while the outcomes are expected to provide significant information relevant to evaluation and management of hearing loss, which has great potential benefit.

STATISTICAL ANALYSIS PLAN

The study design is a prospective, non-randomized, within-subjects comparison of our PSAP intervention. Given the inclusion criterion of, "adults who report having difficulty listening in some daily listening situations," we anticipated that subjects will have varied hearing thresholds across frequencies, from normal through moderate hearing loss, that may impact data analysis for the outcome measures. Therefore, the power analysis prospectively included three groups of hearing levels based on the American Speech Language Hearing Association classifications: normal hearing (≤25 dB HL), mild hearing loss (26-40 dB HL), and moderate hearing loss (41-55 dB HL).

The speech perception test protocol proposed for this study is the same as used by Reed et al. (2017) for their study comparing PSAP and hearing aid performance in adults with mild to moderate hearing loss.[8] Based on the Reed et al. results comparing two types of amplification (i.e., mid-range PSAP and hearing aid), the anticipated effect size for this study was approximated at 4.3% (±3 SD). The sample size calculation for Analysis of Variance (ANOVA) for 3 groups, effect size of 4.3, SD 3, power of .8, and alpha .05 was 11 subjects per group, for **a total enrollment of 33 subjects**.

Data will be analyzed using one-way repeated measures ANOVA comparing within-subject means for the conditions as defined within each primary and secondary outcome measures.

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Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

Personal Sound Amplification Device

Christina Runge, PhD
Otolaryngology
(414) 955-0822
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

Amplification – the process of increasing the volume of sound.
Speech perception- hearing words through a speaker and repeating what is heard.

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Purpose

This project is being done to help patient have better speech understanding.

Length

- You will be in this research project for about one hour.
- This is a one-time appointment.

Procedures *or* Activities

We will ask you to repeat words both using your hearing aids and using a personal sound amplification device.

List of visits:

- Testing appointment
  - Total Number: 1
  - Total Time: One hour

Procedures/Activities that will occur at various visits:

Invasive Procedures/Activities

- None

Non-invasive Procedures/Activities

- Speech perception

Risks

This is a brief list of the most commonly seen side effects/risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Study risks:

- Patients may become bored with the testing.
- There is a higher chance of a potential loss of confidentiality because additional individuals are handling a subject's data.

Benefits

This project may or may not help you, but we hope the information from this project will ultimately help patients hear better.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Dr. Runge at (414) 955-0822

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you report difficulty hearing in some daily listening situations.

A total of about 100 people are expected to participate in this research at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Dr. Christina Runge in the Department of Otolaryngology. A research team works with Dr. Runge. You can ask who these people are.

This study is sponsored by the National Institute of Health.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is help patients have better speech understanding.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

You will have a hearing test in the clinic. The hearing test lasts about 10 minutes. You will be asked to repeat sentences using your hearing aid and complete three questionnaires. You will be asked to repeat the sentences again using a personal sound amplification device and complete the same three questionnaires.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about one hour. This is a one-time appointment.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the project at any time for any reason without your consent. She will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research doctor or a member of the research team immediately if you experience any problems.**

Questionnaires: You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project will not help you, but we hope the information from this project will help patients have better speech understanding.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Runge.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will receive a $50 gift card to either Target or Walmart.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. Whether or not you join this project, your usual medical services will not change

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

After the project has been completed, we will notify you of the results.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Runge at (414) 955-0822.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Runge at (414) 955-0822.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical records, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate-Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this project is:

⇨ Audiology records.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who are not part of the research team because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

University of Wisconsin-Milwaukee
Ascending Hearing Technologies, LLC

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record or BloodCenter blood donor record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Runge at 8701 Watertown Plank Rd., Milwaukee, WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**