Informed Consent Document

Project Title: Improving Access and Affordability of Hearing Healthcare: Effectiveness of Community-based Interventions in West Central and South Alabama

Clinical Trials ID: NCT04671381

Informed Consent

Please read this informed consent carefully before you decide to participate in the study.

Consent Form Key Information:

- **Some people will complete a training program or be compared to those who complete a training program.**
- **Some people will have their hearing tested.**
- **Some people may participate in an Over-the-Counter Hearing Aid clinical trial.**

Purpose of the research study: The main purpose of this study is to understand how we can help people with hearing loss who live in small towns.

What you will do in the study:

- Some will complete in-person training sessions and surveys to help those with hearing loss, or you might be asked to complete surveys without receiving training.
- Or, you might be asked to have your hearing tested and complete some questionnaires about your health. If you have hearing loss you might be asked to participate in a clinical trial with Over-the-Counter Hearing Aids. As part of the clinical trial, you will complete hearing tests, surveys, and attend informational and hearing support sessions

Time required for the study:

- For those participating in the training sessions, you will complete four days of training, each 2 – 3 hours in length. If you are completing only the training surveys, it will take about 20 minutes.
- If you participate in the hearing test and complete the questionnaires it will take about 30 minutes.
- If you participate in the Over-the-Counter Hearing Aid clinical trial, it will take about 1-hour each week for 14 weeks. You also might be asked to complete some surveys and listening tests one or two years after you participate in the clinical trial.

Risks: There is a small chance that some questions on the surveys or some parts of the discussion will make you feel uncomfortable. You can leave at any time during the discussions, the hearing testing, or the clinical trial.

Benefits: If you participate in the clinical trial, you will receive help for your hearing loss. For those not in the clinical trial, there are no direct benefits to you for participating in this research study. The study may help us understand how to help people with hearing loss.

Confidentiality: We will assign you a coded number and will not use your name on any data. This number will be used for record-keeping and data analyses. We will not use any identifying information, such as your initials or your birthdate, for this code. We will keep the list connecting your name to your

code in a locked file. We will destroy this list when the study is completed. We will destroy the tape recordings of discussions right after we listen to them.

Voluntary participation: Your participation in the study is completely voluntary.

Right to withdraw from the study: You can withdraw from the study at any time without penalty. If you want to withdraw and you provided information, we will not use it.

How to withdraw from the study: If you want to withdraw from the study, tell the researcher and leave the room. There is no penalty for withdrawing. If you would like to withdraw after testing, please contact Marcia Hay-McCutcheon at mhaymccu@ua.edu or 205-348-4572.

Compensation/Reimbursement: You will receive a $10 gift card for participating in the hearing test and completing the questionnaires. For completing the training surveys without participating in the training sessions you will receive a $50 gift card. You will receive two Over-the-Counter Hearing Aids if you participate in the clinical trial. For completing the surveys, the information sessions, and follow-up testing with the clinical trial, you will receive two $50 gift cards. If you withdraw before you complete the interview or discussion, hearing testing and questionnaires, or the clinical trial you will still receive full compensation and be allowed to keep the hearing aids.

If you have questions about the study or need to report a study related issue please contact:
Name of Principal Investigator: Marcia Hay-McCutcheon, Ph.D.
Title: Professor
Department Name: Communicative Disorders
Telephone: 205-348-4572
Email address: mhaymccu@ua.edu

If you have questions about your rights as a participant in a research study, would like to make suggestions or file complaints and concerns about the research study, please contact:
The University of Alabama Office for Research Compliance at (205)-348-8461 or toll-free at 1-877-820-3066. You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://research.ua.edu/compliance/irb/. You may email the Office for Research Compliance at rscompliance@ua.edu.

Agreement:

☐ I agree to participate in the research study described above.

☐ I do not agree to participate in the research study described above.

Signature of Research Participant Date

Print Name of Research Participant

Signature of Investigator or other Person Obtaining Consent Date

Print Name of Investigator or other Person Obtaining Consent

We might want to contact you in the future to ask you to participate in other research studies that we are doing. If you would like to be contacted, please tell us how to contact you below.

Signature of Research Participant Date

Do you want us to contact you by phone or email or both?

Phone_____

Email_____