Title: INFORMED CONSENT FORM

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UNIVERSITY of SOUTH FLORIDA
USF RESEARCH & INNOVATION

Informed Consent to Participate in Research Involving Minimal Risk and Authorization to Collect, Use and Share Your Health Information

Information to Consider Before Taking Part in this Research Study

Title: ***Development and Assessment of a Spanish-Language Toolkit for Hearing Loss Self-Management, Aim #2***

Study # 000459

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Michelle Arnold, Au.D., Ph.D. who is an assistant professor at the University of South Florida. This person is called the Principal Investigator. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at USF in the Auditory Rehabilitation and Clinical Trial lab and is supported/sponsored by the National Institutes on Deafness and Other Communication Disorders, which is part of the National Institutes of Health (NIH). The purpose of the study is to develop and test Spanish-language patient education materials for hearing loss. First, we want to find out what people who speak Spanish think should go into these materials from focus groups. Next, we want to find out if people who speak Spanish have a better understanding of hearing loss and options for hearing loss help after receiving these materials. You are being asked to participate in the second part of this study.

Subjects: You are being asked to take part because you are an adult aged 50 years or older who speaks Spanish fluently, and you believe you have limited ability to speak, understand, read, or write in English. We want to make hearing loss education materials for Spanish speakers who may not be fluent in English, or who prefer this type of information in Spanish.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. There are no alternatives to participating in the study.

If you are a USF employee, your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities. If you are a USF student, your decision to participate or not to participate will not affect your student status, course grade, recommendations, or access to future courses or training opportunities.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate.] You will be compensated $25.00 in the form of a gift card after each study session you attend for your participation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study

information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Why are you being asked to take part?

You are being asked to take part in this study because you are a fluent Spanish speaker. There is a lack of hearing loss education materials for Spanish-speakers in the US. We believe that by developing and testing patient education materials that are culturally and language appropriate, we will be helping increase hearing loss understanding for Spanish-speakers who are not fluent in English.

Study Procedures:

If you agree to take part in this study, you will be asked to:

- Attend two, 1 to 1.5 hour individual sessions (possible 3 hours total time commitment). You will have the option to attend the 2nd session remotely, either via a video-conference using a secure platform or over the phone.
- In the first session, you will be randomized to a group. This means that the group you get will be by chance. One group is an experimental group, and those individuals will receive hearing loss information that was developed by our research team. The other group is a control group, and those individuals will receive hearing loss information that was developed by the American-Speech-Language-Hearing Association. You have an equal chance of being in either group. When the study is over, you will also have the opportunity to receive the information that the group you were not in received. Regardless of what group you are in, both groups will:
    - Receive a hearing test in a sound booth. During this test, we will look in your ears with a light to make sure they are healthy. Then, we will test how your eardrum works. Last, you will wear headphones and respond to tones and words that you hear.
    - Complete a series of questionnaires. These ask questions about your ears and hearing, and general healthcare questions.
    - Choose up to 3 areas that you would like to understand more about hearing loss and better hearing
    - *The experimental group (selected by chance)* will review picture-based patient education materials, developed by our research team, in Spanish with a bilingual researcher.
    - *The control group (selected by chance)* will receive word-based patient education materials in Spanish, developed by the American-Speech-Language-Hearing Association, <u>but will not</u> review them with the bilingual researcher.
- In the second session, both groups will:
    - Have the opportunity to review the patient education materials they received with the bilingual researcher
    - Complete a series of questionnaires. The questionnaires will ask about your confidence in managing hearing loss and beliefs you have about hearing loss.

Total Number of Subjects

About 110 individuals will take part in this study at USF. For Aim #2, the part that you are being asked to join, up to 60 individuals will participate.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. If you are a USF student, your decision to participate or not to participate will not affect your student status (course grade). If you are a USF employee, your decision to participate or not to participate will not affect your job status.

Benefits

We are unsure if you will receive any benefits by taking part in this research study. You may benefit from learning more about hearing and hearing loss management as part of this study.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study. However, the following risks may occur:

- You may be bored with the study procedures. We cannot tell in advance if this will occur. You are free to take breaks as needed or withdraw from the study at any time.
- Your personal information might be revealed on accident as part of this study. We take many precautions to make sure this does not happen. Your name is not included on any of the data we collect about you as part of this study. All of your files and records are kept in locked, secured offices. Only approved study team personnel have access to your files and records.
- If you receive a hearing test as part of this study, you might find that some of the procedures are mildly uncomfortable. You do not have to continue with any procedures that cause mild pain or discomfort and still be in the study.

Compensation

You will be compensated $25.00 in the form of a gift card for each scheduled study visit you attend.

If you are a USF employee, to receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid. If you do not want to complete the tax payer ID form you can still participate in the study, however if the form is not completed you will not be compensated.

Costs

It not cost you anything to take part in the study. If you are unable to arrange or pay for travel to and from the focus group sessions, you can receive a $20 travel voucher each way for a ride-sharing service, such as Lyft or Uber.

Conflict of Interest Statement

There are no conflicts of interest on the part of the PI or any member of the study team related to this study.

Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

- The research team, including the Principal Investigator, study coordinator, research assistants, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.
- The National Institutes on Deafness and Other Communication Disorders (NIDCD), who are supporting this research with a grant. The institution will be reimbursed by the NIDCD for use of this site's facilities and for the work the research staff does for this research.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are. Your information collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies unless allowed by law.

Although the technology we use to deliver services over the internet is secure, it is possible, although unlikely, that unauthorized individuals could gain access to your information. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this study involves risks similar to a person's everyday use of the Internet.

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The

researchers would like to remind you to respect the privacy of your fellow subjects and not repeat what is said in the focus group to others.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Michelle Arnold, principal investigator at (813) 974-1262. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The study team personnel staff that are part of this research study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project.

This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a subject in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke your authorization, please write to:

Principal Investigator
For IRB Study #000459
4202 E. Fowler Ave.
PCD 1017
c/o ARCT Lab
Tampa, FL 33620

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study]. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

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Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent