

ANCILLARY REVIEWS

Which ancillary reviews do I need and when do I need them?			
Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	Does your study...	If yes...	Impact on IRB Review
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Include Gillette resources, staff or locations	<i>Gillette Scientific review and Gillette Research Administration approval is required. Contact:</i> research@gillettechildrens.com	Required prior to IRB submission Approval must be received prior to IRB committee/ designated review. Consider seeking approval prior to IRB submission.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Involve Epic, or Fairview patients, staff, locations, or resources?	<i>The Fairview ancillary review will be assigned to your study by IRB staff</i> <i>Contact: ancillaryreview@Fairview.org</i>	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	<i>STOP – Complete the Medical Template Protocol (HRP-590)</i> <i>The regulatory ancillary review will be assigned to your study by IRB staff</i> <i>Contact: medreg@umn.edu</i> <i>See https://policy.umn.edu/research/indide</i>	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Require Scientific Review? Not sure? See guidance on next page.	ONLY REQUIRED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	<i>Complete the CPRC application process.</i> <i>Contact: ccprc@umn.edu</i>	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	<i>Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee.</i> <i>Contact: barmstro@umn.edu</i>	Approval from these committees must be received

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<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	Complete the CMRR pre-IRB ancillary review Contact: ande2445@umn.edu	prior to IRB approval; These groups each have their own application process.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents?	STOP – Complete the Medical Template Protocol (HRP-590)	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	STOP – Complete the Medical Template Protocol (HRP-590)	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Include PHI or are you requesting a HIPAA waiver?	If yes, HIPCO will conduct a review of this protocol. Contact: privacy@umn.edu	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Use data from the Information Exchange (IE)?	The Information Exchange ancillary review will be assigned to your study by IRB staff Contact: ics@umn.edu	Approval must be received prior to IRB approval. These groups do not have a separate application process but additional information from the study team may be required.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Use the Biorepository and Laboratory Services to collect tissue for research?	STOP – Complete the Medical Template Protocol (HRP-590) The BLS ancillary review will be assigned to your study by IRB staff. Contact: cdrifka@umn.edu	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Have a PI or study team member with a conflict of interest?	The Col ancillary review will be assigned to your study by IRB staff Contact: becca002@umn.edu	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Need to be registered on clinicaltrials.gov?	If you select “No” in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff Contact: kmmccorm@umn.edu	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Require registration in OnCore?	If you select “No” or “I Don’t Know” in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff Contact: oncore@umn.edu	

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PROTOCOL COVER PAGE

Protocol Title	A system and process to improve the satisfaction with hearing health products
Principal Investigator/Faculty Advisor	Name: Peggy Nelson
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Student Investigator	
Scientific Assessment	Nationally-based, federal funding organizations
Version Number/Date:	Version 3, September 2023

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1 (v2)	10/27/20	Responded to questions from 10/12	Y
2 (v3)	12/14/20	Responded to questions, new consent template	y
3 (v4)	1/19/21	Responded to questions, amended consent, requested info from privacy@umn.edu	y
4 (v 5)	2/18/21	Minor changes to email process, removed HIPAA waiver	n
5 (v 6)	3/2/21	Checked HIPAA disclosure form, clarified data shared with Novidan, IDL	n
6	8/5/23	Changed recruitment, changed research team, added Amptify as external partner	y
7	9/22/23	Corrected errors and inconsistencies, clarified that external team member has no other IRB	y
8	1/24/24	Added 'other clinics' to recruitment	y

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ABBREVIATIONS/DEFINITIONS

DTC: direct to consumer

HA: hearing aid

COSI: Client oriented scale of improvement

1.0 Objectives

- 1.1 Purpose: Dr. Nelson, Dr. Karen Lawson, Dr. Timothy Beechey and Innovative Design Labs Inc. (IDL) proposes to create a cloud-based system which integrates advances and techniques from Health and Wellness Coaching (HWC) into the Hearing Aid (HA) fitting and trial process. We hypothesize that the integration of Health and Wellness Coaching, aided by cloud-based tools, into this process will increase patients' satisfaction and usage of hearing health products.

2.0 Background

- 2.1 Significance of Research Question/Purpose: The proposed clinical trial aims to determine the effectiveness of the proposed system to affect the hearing aid use and perceived quality of treatment provided by hearing aid users. This will add to the body of evidence both for the benefit of ongoing counseling of hearing aid patients and the effectiveness of health coaching for chronic conditions. Clinically meaningful outcomes for hearing aid users will be measured using a sufficiently powered sample size that can detect a meaningful difference. Inclusion and exclusion criteria are described in the attached Clinical Trial sections.
- 2.2 Preliminary Data: N/A
- 2.3 Existing Literature: As of 2015, 28.8 million U.S. adults could benefit from using hearing aids and the prevalence of hearing loss in the United States is predicted to rise significantly due to an aging population and the growing use of personal listening devices. However, only 28.5% of individuals who could benefit from a HA actually wears one. The non-use of hearing aids by people with hearing loss has many far-reaching implications for their physical health, mental health, and their social life. As the market moves towards a, direct-to-consumer distribution model following the 2017 FDA directive, more patients will be receiving therapy for hearing loss. While in traditional practice, an audiologist assists the patient with support adjusting to their new therapy, there is no person fulfilling that role in the direct-to-consumer model. Hypothesis: We hypothesize that the integration of Health and Wellness Coaching, aided by cloud-based tools, into this process will increase patients' satisfaction and usage of hearing health products

3.0 Study Endpoints/Events/Outcomes

- 3.1 Primary Endpoint/Event/Outcome: We will test all participants for Client-oriented scale of improvement (COSI), and hours of hearing aid use. We will test all participants at the time of recruitment and 3 months post-fitting. We will analyze the data for: Change in COSI goal achievement, Change in AQoL-8D score, hours of HA use. The Client Oriented Scale of Improvement (COSI) is a clinically accepted outcome measure tool that fits well with the goal of the study as it measures the goal progress and perceived improvement in hearing ability of the patient. This questionnaire tracks the goals and needs of the patient through their fitting process. It allows the patient to qualify their degree of change for each of their needs/goals

as "Worse", "No Difference", "Slightly Better", "Better", or "Much Better" and their hearing ability.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): assessment of quality of life (AQoL), The Assessment of Quality of Life (AQoL) is a measure of health-related Quality of Life. AQoL-8D covers dimensions of Independent Living, Happiness, Mental Health, Coping, Relationships, Self-Worth, Pain, and Senses.

3.3

4.0 Study Intervention(s)/Interaction(s)

5.0 Description: The proposed clinical trial aims to determine the effectiveness of the proposed system to affect the hearing aid use and perceived quality of treatment provided by hearing aid users. This will add to the body of evidence both for the benefit of ongoing counseling of hearing aid patients and the effectiveness of health coaching for chronic conditions. Clinically meaningful outcomes for hearing aid users will be measured using a sufficiently powered sample size that can detect a meaningful difference.

5.1 Study Design: The study will recruit 60 hearing aid users which will be randomized to two groups: a control group receiving standard of care and a group with the proposed health coaching system. The study will emulate the direct-to-consumer (DTC) experience as closely as possible while maintaining appropriate subject protections. Participants with self-reported mild to moderate hearing loss (matching the expected DTC market) will be recruited. Hearing loss will be measured using standard practice (i.e. Real-ear measurements) for later result analysis, but not used to adjust fit. Groups will be matched for hearing loss severity, age, and gender.

5.2 Study Procedures: Both group one and group two will be provided with hearing aids designed for the direct-to-consumer market, manufactured by Novidan. As is typical with DTC hearing aids, they come with a "generic" fit designed to approximate the needs across a large portion of the hearing aid population. After recruitment and consent (which will occur largely over Zoom and telephone, the devices will be supplied to the participants by mail rather than in-person to emulate a web-based purchase of DTC hearing aids.

DTC fitting involves using participants' self-reported hearing status to set baseline hearing aid settings. Hearing aids are adjusted following initial fitting during a zoom session with an audiologist. These procedures are currently being used in clinical settings during the pandemic. Both groups will be able to use a companion smartphone application which can control basic hearing aid functions and features such as volume, noise reduction, environment classification, profile mode, equalizer, etc. Both groups will have access to the audiologist for the first session and one followup session. However, only group 2 will have the health coaching (HWC) functionality of the application enabled and visible.

Group 1: Control: This group will be supplied with Novidan DTC hearing aids and documentation following standard of care as a control. They will be provided with the

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mobile application allowing for the monitoring of data for study analysis and personal control of their hearing aids, but not HWC features.

Group 2: HWC Intervention: This group will also be supplied with the Novidan DTC hearings aids and documentation, same as the control group, but will be supplied the enhanced mobile application that allows for participation in health coaching features. They will be assigned to a health coach and will have coaching sessions scheduled.

Health Coaching is a methodology that differs from health education or counseling. It builds on a foundation of fifty years of research in adult development, social psychology, organizational leadership, behavioral and positive psychology, and neuroscience. Theoretical models that inform coaching include self-determination theory, motivational interviewing, transtheoretical model, social cognitive theory, internal family systems, locus of control, and nonviolent communication. Health Coaching competencies translate the scientific foundation of theory and research into relationships designed to facilitate lasting changes of mindset and behavior. Health Coaches assume that people have strong intrinsic resources and strengths, can access the self-motivation needed to function autonomously and competently, and are able to realize positive change within a safe and confidential alliance, where they are inspired, respected, and supported.

The primary goal of the health coaching will be connecting the client's values and desires for optimal wellbeing to their consistent use of their HAs. The coaches focus on nurturing client self-empowerment so that they are equipped and supported to make optimal behavioral and health care decisions. Additionally, the coaching would address the psychosocial aspects of having a HA, and the ability to discuss problems about their HAs with professionals in an effective manner.

For the purposes of this study, 1-2 credentialed health coaches (minimum requirement of bachelor's degree and NBC-HWC) will be employed under the budget plan of the study, and they will be trained to provide coaching support specifically for this population, with an understanding of the nature of the study. A bio-profile of the health coach(s) will be made available in the client information materials. Volunteers for the study will have agreed to be randomized to an arm that either does or does not include coaching. To participate in the coaching arm, they will have to commit to a minimum of 4 visits over 60-90 days, but will have availability, at their own discretion, to access the coach as often as it serves their progress, with a maximum of 8 visits in 90 days. After completion of initial assessment instruments, participants will be connected with their coach virtually through the developed platform. The health coach will review the coaching agreement and consent to record the coaching session (if applicable). If the coaching session is recorded (optional) they will obtain consenting virtual signatures from clients. Sessions will be up to 50 min. for the initial session, and 20-30 min. for follow-ups, and provided through a virtual A/V platform. Scheduling with their coach will also be managed through the developed platform. Coaching notes and instruments will be completed within the communication platform, and will be accessible to the coaches and researchers only.

Data Collection and Analysis: We will test all participants for Client-oriented scale of improvement (COSI), assessment of quality of life (AQoL), and hours of hearing aid use. All surveys will be completed remotely. Participants will have the option of completing them using a fillable online form delivered via email, or using pen/paper through the mail. We will test all participants at the time of recruitment and 3 months post-fitting.

Note: the AQoL survey asks “do you ever feel like hurting yourself?” If the participant answers “often or all the time” we will follow up:

Please check the most appropriate box:

- A. I have a professional mental health provider and have adequate, on-going care. **No intervention needed.**
- B. I have a primary care physician who is helping me manage my mental health challenges. **No intervention needed.**
- C. I have a primary care provider or clinic, but I have not engaged with them around my mental health. **Please contact your provider to be seen urgently about your thoughts of self-harm.**
- D. I have health insurance, but no regular provider. **Please contact your insurance provider and ask for urgent referral for mental health services.**
- E. I have no resources or support for mental health services. **Please contact the NAMI MN Crisis number for immediate support: **274747 or text MN to 741741**

At the end of the study, participants will be asked if they’re willing to answer some open ended questions regarding the app. This will be done by study personnel via zoom, phone, or in person. These include:

- how easy was the app to use
- what challenges did you experience
- do you have any suggestions or comments

5.3 Individually Identifiable Health Information: We will obtain audiometric hearing thresholds directly from participants. We have completed the HIPCO survey and that is attached.

6.0 Data Banking: N/A

7.0 Sharing of Results with Participants: N/A

8.0 Study Duration

8.1 Describe:

- Individual participants will be followed for 3 months post-fitting.
- All study participants will be enrolled within 18 months

- The project will last 2 years.

9.0 Study Population

- 9.1 Inclusion Criteria: Age 18 – 85 years, with hearing loss appropriate for DTC hearing aids and cognitive abilities to use the software.
- 9.2 Exclusion Criteria: inability to use the software with standard assist
- 9.3 Screening: Hearing will be screened remotely and ability to use the software will be monitored by study staff.

10.0 Vulnerable Populations: N/A

11.0 Number of Participants

- 11.1 Number of Participants to be Consented: 60-80 participants will be consented

12.0 Recruitment Methods

- 12.1 Recruitment Process: We will recruit participants through Amptify clinics and through U of M and related clinics. Clinical audiologists involved in fitting devices through partner Amptify clinics and through related clinics will recruit 5 – 10 participants each. We will use HearingTrial.com (see attached) to screen. Clinics will be reimbursed \$150 for each participant recruited.
- 12.2 Source of Participants: There will be no other source for recruiting participants.
- 12.3 Identification of Potential Participants: Participants will self-identify, and we will follow up with audiologic testing to confirm eligibility. Dr. Nelson, Dr. Conchas or Dr. Teece will make initial contact with potential participants.
- 12.4 Recruitment Materials: Attached
- 12.5 Payment: Participants will be paid \$150 upon completion of the project.

13.0 Withdrawal of Participants

- 13.1 Withdrawal Circumstances: Participants will be withdrawn if they do not wear the hearing devices within 2 weeks of fitting.
- 13.2 Withdrawal Procedures: If participants withdraw we will not continue to collect data or to use their data.
- 13.3 Termination Procedures: Same as above.

14.0 Risks to Participants

- 14.1 Foreseeable Risks: There are no foreseeable risks.
- 14.2 Reproduction Risks: N/A
- 14.3 Risks to Others: N/A

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits: There are no foreseeable benefits to participation.

17.0 Statistical Considerations

17.1 Data Analysis Plan: The UMN will recruit up to 60 participants with mild to moderately severe hearing loss who are representative of the direct-to-consumer hearing aid market. We will attempt a rolling enrollment with two arms randomized between hearing aid without health coaching (control) and hearing aid with health coaching.

17.2 Power analysis: In recent studies examining the effects of counseling on hearing aid satisfaction [41] showed a 16% and 18% improvement in hearing aid satisfactions after 1 and 2 sessions respectively when using goal-oriented counseling compared to standard of care informational counseling. Based on this study we have estimated an effect size of .55 relative to baseline measures of COSI of 3.77 from [53]. With this effect size a sample of 58 individuals will provide 80% power at the $p < 0.05$ level. For this reason, we plan to collect data in a total of 60 subjects. To ensure we reach the necessary number of participants extra individuals will be recruited if we have participants drop out of the study.

17.3 Statistical analysis: At the conclusion of the study, the usual descriptive statistics and graphs (as appropriate) will be generated. The primary HA outcomes of hours of HA use (data-logged), HA perceived benefit (COSI), and quality of life metrics (AQoL) will be analyzed using linear regression models with the group as the single predictor and the group adjusted with additional variables such as demographic (age, sex, etc.) Relevant analyses will then be repeated for identified subgroups in the main study. All analyses will be conducted at $\alpha=0.05$ level of significance using R statistic software.

17.4 Data Integrity: Dr. Nelson will be responsible for data checking and integrity.

18.0 Health Information and Privacy Compliance

Individually Identifiable Health Information: for guidance regarding the use, collection, storage and sharing outside of the covered entity of identifiable health information please see: [UMN Privacy Office Policies](#) and/or [Fairview Health Services Privacy Policies](#), and [UMN HIPAA Agreement Templates](#). For research conducted at Gillette Children's Specialty Healthcare refer to [Gillette Research Administration](#) for guidance.

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

18.1 Select which of the following is applicable to your research:

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- ☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.
- ☒ I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).
- ☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

- ☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

- ☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me
- ☒ I will collect information directly from research participants.
- ☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.
- ☐ I will pull records directly from EPIC.
- ☐ I will retrieve record directly from axiUm / MiPACS
- ☐ I will receive data from the Center for Medicare/Medicaid Services
- ☐ I will receive a limited data set from another institution

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

18.4 Approximate number of records required for review: N/A/

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

- ☐ This research involves record review only. There will be no communication with research participants.

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- ☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.
- ☒ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.
 - We will communicate with participants using encrypted email (Proofpoint) and zoom during the COVID period. We have read email and zoom policies and will abide by those.

18.6 Access to participants

We will not access any medical records not provided by participants themselves.

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

- ☐ In the data shelter of the [Information Exchange \(IE\)](#)
 - ☐ Store ☐ Analyze ☐ Share
- ☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database
 - ☐ Store ☐ Analyze ☐ Share
- ☒ In REDCap (recap.ahc.umn.edu)
 - ☒ Store ☒ Analyze ☒ Share
- ☐ In Qualtrics (qualtrics.umn.edu)
 - ☐ Store ☐ Analyze ☐ Share
- ☐ In OnCore (oncore.umn.edu)
 - ☐ Store ☐ Analyze ☐ Share
- ☐ In the University's Box Secure Storage (box.umn.edu)
 - ☒ Store ☒ Analyze ☒ Share
- ☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:
 - ☐ Store ☐ Analyze ☐ Share
- ☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☐ Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐ I will use a server not previously listed to collect/download research data

☐ I will use a desktop or laptop not previously listed

☐ I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐ I will use a mobile device such as a tablet or smartphone not previously listed

18.8 Consultants. Vendors. Third Parties. N/A

Novidan, Inc is a vendor providing the hearing devices. Innovative Design Labs is the PI

18.9 Links to identifiable data: N/A

18.10 Sharing of Data with Research Team Members. De-identified data will be shared with Novidan and IDL team members using Box.

18.11 Storage and Disposal of Paper Documents: Paper files with identified data will be stored in a locked box in Elliott Hall S30. They will be shredded 7 years after completion of the study.

19.0 Confidentiality

19.1 Data Security: Only de-identified data will be shared on Box. Identified data will be on paper only, locked in the Elliott hall cabinet.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

The study has minimal risk. Data will be monitored by Dr. Nelson. The safety of the participants will be monitored by Dr. Nelson.

20.1 Data Integrity Monitoring.

Dr. Nelson will check the data monthly and will discuss with the team in monthly meetings

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Data Safety Monitoring.

Dr. Nelson will check the data monthly and will discuss with the team in monthly meetings

21.0 Compensation for Research-Related Injury N/A

22.0 Consent Process

We will follow “SOP: Informed Consent Process for Research (HRP-090)” and “SOP: Written Documentation of Consent (HRP-091).”

22.1 Consent Process (when consent will be obtained):

Consent will be obtained via email and confirmed by phone and zoom during COVID. We will send the consent form and a cover email:

Attached is the consent form. We would like you to read the form, and we are also including a summary here: In order to agree to do the study, in lieu of signing a hard copy consent form (which you can do if you print, sign, scan and email it back to me) I will ask you to send me a brief description of the study as well as specific statement:

"I have read the consent form for the study. I have discussed the project with a member of the research team. I agree to participate in this study. I understand that I may withdraw at any time without prejudice."

If you have any questions or comments let me know! Once you send me your consent statement we can go from there and set up a first meeting.

•

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

•

22.3 Adults Unable to Consent: (N/A)

23.0 Setting

23.1 Research Sites: The University Center for Applied and Translational Research will recruit all participants and will conduct all studies. Research will happen in CATSS or in the participants' homes through remote connection.

24.0 Multi-Site Research N/A

25.0 Coordinating Center Research N/A

25.1

26.0 Resources Available

Resources Available: We will be working with Innovative Design Labs (health coaching software developer), and Novidan, Inc (hearing aid hardware provider)

27.0 References

Bainbridge, K.E. & Ramachandran, V. (2014). Hearing aid use among older United States adults: The National Health and Nutrition Examination Survey, 2005-2006 and 2009-2019. *Ear and Hearing* 35 (3) 289-294. doi:10.1097/01.aud.0000441036.40169.29

Cox, RM, & Alexander, GC. (1995) The abbreviated profile of hearing aid benefit. *Ear and Hearing* 16. 176-186.

Cox RM, Alexander GC. (1999) Measuring Satisfaction with Amplification in Daily Life: the SADL scale. *Ear Hear.* 20(4):306-20.

Dillon, H. (1997) Client Oriented Scale of Improvement (COSI) and its relationship to several other measures of benefit and satisfaction provided by hearing aids *J Am Acad Audiol* 8(1):27-43.

Nelson, P., Gregan, M., Perry, T., & VanTasell, D. (2018) "Self-adjusted amplification parameters produce large between-subject variability and preserved speech intelligibility in noise", *Trends in Hearing*. 22. 1 – 13. doi.org/10.1177/2331216518798264