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# Research Subject Informed Consent Form

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| **Title of Study:** | Feasibility of a Hearing Program in Primary Care for Underserved Older Adults #S23-00648 |
| **Principal Investigator:** | David R Friedmann, MD, MSc<br>Department of Otolaryngology-Head & Neck Surgery<br>NYU Grossman School of Medicine<br>550 1st Ave<br>Skirball Suite 7Q<br>NY, NY 10016<br>212 263 5565 |
| **Emergency Contact:** | David R Friedmann, MD Msc<br>212 263 5565 |

## 1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

## 2. What is the purpose of this study?

The purpose of this study is to test the feasibility of a hearing screening program in a public hospital-based setting for older adults as well as to determine the feasibility of providing counseling on alternative hearing health strategies in people who screen positive for hearing loss compared to people who receive an audiology referral alone.
You are being asked to participate in this study because you are 60 years of age or older.

## 3. How long will I be in the study? How many other people will be in the study?

The expected duration of an individual subject's involvement with the study is 3 months

Total duration of study is 2 years

120 subjects are expected to enroll in this study

## 4. What will I be asked to do in the study?

If you agree to be in this research study and sign this consent form, the following will happen:

We will screen primary care clinic patients who are ≥60 years old. We will approach patients in the waiting room in Bellevue primary care clinics and request participation in a hearing assessment. The research assistant (RA) will bring you to a quiet room in the clinic to complete the assessments. You will first complete the subjective a questionnaire about whether hearing loss impacts different aspects of your daily life on a tablet to record your responses so your experience with objective testing will not bias self-reported results. We will also objectively assess your hearing using a portable audiometer on a tablet. You will be asked to wear a pair of headphones and identify when you hear sounds. This test will determine the presence and severity of hearing loss. You will also receive a single page infographic promoting best communication strategies for hearing loss.

All patients with positive hearing screen for disability (HHI score >10) or who test positive for hearing loss (>40 decibel (dB) loss in both ears) and meet inclusion criteria will be offered the opportunity to participate before or after their primary care visit. After informed consent is obtained, we will conduct an intake survey of demographics (information about you like age, gender, race, ethnicity) and hearing history (<5 minutes). We will randomize (assign by chance, like flipping a coin, in a 1:1 ratio) participants to either 1) a 30-minute counseling and tutorial session on alternative accessibility options for hearing augmentation/rehabilitation in addition to a referral to audiology or, 2) to receive referral to audiology alone as is the conventional care pathway.

For those randomized to counseling, the session will begin by reviewing educational strategies to enhance auditory-verbal communication. If present, a care partner will be invited to take part in the tutorial. Then, intake questions related to the participant's experience using technology such as smartphones will be reviewed and tailor the demonstration of accessibility features for either Apple iOS and Google Android. We will demonstrate features for 1) sound amplification with the device's microphone along with wired headphones (that we will provide) as well as 2) live caption/transcription services available on these platforms.

Printed step by step instructions and links to online instructions will also be provided for your reference. We may also review optional input of measured hearing profiles for frequency-specific gain tailored to your comfort with the technology and based on hearing loss pattern.

If approaches using a smart phone are not preferred, a PocketTalker™ and other personal sound amplifier products will be demonstrated along with information about how to access, purchase or request these devices.

We will follow up with you within 72 hours after your visit to ensure understanding of the recommendations, be it referral to audiology or any questions about the counseling session and use of personal amplification devices.

We will also follow up at 3 months to complete a survey on what if any recommendations you have followed and we will assess the subjective impact of this approach on hearing and communication by repeating the HHI-S.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

We will also recruit 10 participants from each randomization arm to provide additional feedback about your experience at 3-month follow up. You do not have to agree to complete this additional interview if you do not want to. The study team will inform you if we are still recruiting for additional interviews and ask you if you would like to participate at your 3-month follow-up visit.

## 5. What are the possible risks or discomforts?

The screening procedures pose minimal or no risk, obtaining patient consent is primarily for data collection purposes. Additional demographic data will only be collected for those recruited to be randomized for the intervention. There is a small risk of loss of confidentiality when participating in a research study; however, your information will be labeled with a unique code that does not contain your identifiable information. The key linking this code and your identifiable information is stored securely and separately from your data and only accessible to the study doctor and his team.

## 6. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available…

## 7. What are the possible benefits of the study?

As a result of participating in the study, patient subjects will be offered a screening test of hearing and provided educational information about treatment options.

From a societal perspective, we hope to learn whether primary care setting may be an appropriate location to offer hearing screening and rehabilitation options.

## 8. What other choices do I have if I do not participate?

If you do not wish to participate, but have a hearing concern, you do not have to be in this study to have your hearing tested. You will be referred to audiology.

You may also discuss alternatives with your personal physician.

## 9. Will I be paid for being in this study?

All participants randomized in our study will be compensated $25 for their time after completing the 3-month follow up. Those who participate in interviews will be compensated an additional $25 for their time.

You will be paid $25 after completing the 3-month follow up. If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will not receive payment.

If you complete all the study visits, including an interview at the follow up encounter, you will receive *$50* total for being in this study.

As is required by the laws that apply to NYU Langone Health, in order for you to receive a payment (i.e. bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a W-9 form issued by the Internal Revenue Service (IRS). If you do not have either of these numbers or are not willing to complete the W-9, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone Health for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise PI: David Friedmann.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone Health is required to report to the IRS any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W-9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

## 10. Will I have to pay for anything?

There is no cost to participate in this study procedures or tests being done solely for research purposes.

## 11. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

## 12. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

**Certificate of Confidentiality**
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data or documents) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information may be included in your NYU Langone Health electronic medical record

# 13. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute on Aging
- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research
  - H+H personnel responsible for the support or oversight of the study at Bellevue Hospital
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Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

## 14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

## 15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

| Name of Subject (Print) | Signature of Subject | Date |
|---|---|---|

| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date |
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**Witness to Consent Process for Non-English-Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

| Name of Witness (Print) | Signature of Witness | Date |
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