St. Elizabeth's Medical Center
A STEWARD FAMILY HOSPITAL

Steward

Informed Consent to Participate in Research

Subject's Name:	**Date:**
Home Telephone:	**Date of Birth:**
Home Address:	

Research Study Title: Investigation of Anatomical Correlates of Speech Discrimination

Principal Investigator: Mark Parker, Ph.D., CCC-A

Study Sponsor(s): N/A

KEY INFORMATION:

The purpose of this study is to determine which cell types code for speech discrimination in the presence of background noise. Our hypothesis is that while both the sensory cells (cochlear outer hair cells) and the hearing nerve (auditory nerve) are important for hearing-in-noise, outer hair cell loss may explain why many individuals perform poorly in background noise. Additionally, we hypothesize that these individuals may experience increased benefit from hearing aids with noise reduction technology.

The major requirements for participation are that you:

1. are a native English-speaking adult with no known ear disease, and are willing to complete an audiology test battery, or
2. are scheduled to have sinus surgery.

The duration of your participation will range from one to two days, depending upon whether you decide to complete the study in one 2.5 hour session, or whether you want to divide up the study tasks into one 1.5 and another 1 hour session on a different day. Most of your participation will take place in an audiometric sound booth, where you will be asked to complete tasks in both quiet conditions and in competing background noise.

For patients who have been invited to participate because they are scheduled for unrelated sinus surgery, you will receive additional audiological testing while under anesthesia. You will be under anesthesia for an additional 20 minutes beyond the length of your originally scheduled surgery in order to complete the testing.

You may also participate in an optional group wearing hearing aids for 1 month, which will require 3 additional 1 hour visits within this 1 month period. There are no significant health risks associated with participating in this study. The main benefit from participating in this study is that you will help us understand the basic mechanisms of hearing in noise and the most effective means of treating this

disorder.

About this Research Consent Form:
You are being asked to participate in a research study. A research study is the scientific method used to improve medical practice and patient care.

Do I have to participate in this study?
Your participation is voluntary. Taking part in this research study is totally your choice. You can choose whether or not to participate.

If you decide to participate, you can stop taking part in this research study at any time for any reason. If you are thinking about stopping or decide to stop, tell the principal investigator. The principal investigator will make sure that you stop the study safely and talk to you about follow-up care, if needed.

If you decide not to participate in this research study or stop being in this research study, it will not affect how you are treated at St. Elizabeth's Medical Center. Prior to deciding if you should participate in this research study, you should understand enough about the risks and benefits to make an informed decision. This process is called informed consent.

Please take your time to make your decision about taking part in this research study. You may discuss your decision with your family and friends. You can also discuss it with any other health care provider. Please read all of the information contained in this form carefully and ask any questions that you have about this research study. If words or sections are unclear to you, please ask for an explanation.

If you decide to take part in this research study, you will be asked to sign this form and you will be given a copy of the signed form to keep.

The principal investigator has no financial conflict of interest to disclose.

1. Invitation:
You are being invited to take part in a research study involving routine audiology testing and hearing aid fitting because you are an adult with no known otological disease and may be willing to help us understand the cellular basis of hearing in quiet and in background noise.

You may also be invited because you have been scheduled for functional endoscopic sinus surgery, requiring anesthesia, as part of your regular clinical care.

2. Purpose: Why is this research study being done?
The purpose of this study is to gain more information about the biological processes that lead to difficulty hearing and understanding speech, particularly in noisy environments, and effective methods of treating this problem. Our hypothesis is that while both the cochlear outer hair cells and the auditory

nerve are important for hearing-in-noise, outer hair cell loss may explain why many individuals perform poorly in background noise. Additionally, we hypothesize that these individuals may experience increased benefit from hearing aids with noise reduction technology.

3. Procedures: What will happen if you take part in this research study?

As part of the study, you will be asked to report your age, gender identification, gender on listed on your birth certificate (since there are known differences in hearing based on sex), and race. You will receive an audiology test battery. This extended battery will consist of hearing tests in quiet and in competing background noise presented under headphones or through loudspeakers in an audiometric booth, and electroacoustic evaluation where recording electrodes will be placed on your forehead, ear canals, and on the skin behind your ear.

If you are already here for a regular visit, you may complete the study test battery after your routine audiological exam. This battery is for research purposes only and is not part of your routine audiological care.

The audiological test battery includes:

1) Speech –in Noise Assessments to measure of your understanding of speech in the presence of background noise:
    a. QuickSIN, in which you are asked to repeat sentences in the presence of competing sentences of increasing loudness
    b. Time Compressed word recognition in 10% reverberation, in which you are asked to repeat words presented quickly an using reverberation
    c. Word recognition in the presence of 0 dB SNR ipsilateral speech weighted noise, in which you are asked to repeat words in the presence of static noise
    d. Self-rating of hearing-in-noise difficulty, in which you are asked to rate your difficulty hearing in noise on a scale of 1-100
    e. Hearing Handicap Inventory for the Elderly, in which you are asked to self-rate the impairment that any hearing loss may have on your social interactions
2) Cognitive processing using the Dichotic Digit -Directed Recall test, in which you are asked to repeat a sequence of random numbers
3) Central auditory processing using the Dichotic Digit –Free Recall test, in which you are asked to repeat a sequence of random numbers in the presence of background noise
4) Distortion product otoacoustic emission (DPOAE) testing, which measures sensory hair cell function, will be recorded using a probe inserted into your ear canal
5) Electrocochleography (ECochG) testing, which measures brain activity in response to sound, will be elicited using earphones to deliver the acoustic stimuli and measured from electrodes taped to your forehead and on the skin behind each ear

Anesthesia Group (participants undergoing scheduled functional endoscopic sinus surgery):

You will receive additional ECochG testing under anesthesia, prior to the start of your previously scheduled surgery. You will be under anesthesia for an additional 20 minutes in order to complete the

ECochG testing. You may complete the audiological test battery the day before your surgery, if it is convenient to come in on the same day as your pre-op appointment.

Optional portion of this study:
You are also invited to take part in an optional hearing aid study. If you choose not to participate in this optional study, you may still participate in the main study.

Hearing Aid (HA) Groups 1-5: We are testing the effectiveness of 3 features hearing aids use to improve hearing-in-noise performance. After you complete the audiology test battery, you will be fit with Premium level digital hearing aids with one, all, or none of these features enabled depending upon your group assignment, which will be random. Neither you nor the study team will not know what group you are in (or what features enabled/disabled).

You will be required to wear the hearing aids, while you are awake, every day during the one month study period. The hearing aids will be retuned at your final visit, after which time you will be given the option of purchasing a similar set of hearing aids.

You will need to come in to complete the following:

1. a repeat audiology test battery immediately after being fit with the hearings aids,
2. a 1 week re-test,
3. and a 1 month re-test.

In this research study, zero, one, two or all three of the available features will be turned off. This is different than what you would experience during standard clinical care in which all features are typically enabled. Because of this, you may receive little benefit or no benefit from the hearing aids for the month of your study participation. At the end of the study month, we will give you one month during which time your hearing aids will be reprogrammed with all three features enabled, to give you a chance to see if hearing aids can improve your hearing. During this month, if you wish, we can sequentially enable or disable any and all of the available features, as we would as part of standard clinical care. This month will occur at no additional cost. At the end of this month, you have the option of purchasing these hearing aids at the usual cost to you.

☐ Yes, I would like to participate in the optional hearing aid study. Participant Initials: _____

☐ No, I choose not to participate in the optional hearing aid study. Participant Initials: _____

Study Visit Timeline						
	Visit 1 Screening	**Visit 2** Baseline Audiological Test Battery	**Visit 3*** Day of Surgery *Only for Anesthesia Group	**Optional Hearing Aid Study**		
				Visit 4 Initial HA Fitting	**Visit 5** 1 Week HA use	**Visit 6** 4 Weeks HA use
Informed Consent	**X**	**X**				
Audiology Test Battery		**X**				
Electrocochleography (ECochG) Testing Under Anesthesia			**X**			
Hearing Aid Fitting				**X**		
30 Minute Audiology Testing				**X**	**X**	**X**
Hearing Aid Return and Optional Reprogramming of Features for Additional Month						**X**

4. Duration: How long will you be participating in this research study?
Participation will require approximately 2.5 hours for completion of the audiology test battery, which could be completed in 1 day or broken up into 2 sessions.

If you are in the Anesthesia Group, on the day of your surgery, you will be under anesthesia for an additional 20 minutes while the ECochG recordings are obtained

If you are participating in the optional hearing aid study you will be fit with hearing aids and complete 30 minute testing on the day of Initial HA fitting, and will return for 30 minute testing 1 week later and 1 month after your initial fitting.

5. Risks, Discomforts, Side Effects and Inconveniences: What are the risks involved with being enrolled in this study?
There are no known health risks or health benefits associated with baseline test battery or hearing aid use. There is a possible risk of loss of confidentiality. Additionally, several possible sources of discomfort and inconvenience are listed below.

• While sound pressure levels presented in the testing are well below exposures that are known to cause hearing damage, if sound levels ever exceed your comfort level you should immediately contact the study leader.
• You may feel uncomfortable with some of the personal information we request. You don't have to answer any questions that make you feel uncomfortable.
• For subjects with tinnitus (ringing in the ears), it is possible that your tinnitus could get worse over the course of this study as a natural progression of the disease. If this occurs, you should contact the study leader to discuss withdrawal from the study.

Additional Risks for Anesthesia Group:

You have been given a regular clinical care anesthesia consent, which lists the risks of general anesthesia. The same risks that you were counseled about as part of the regular clinical anesthesia consent will apply for the additional 20 minutes of anesthesia required for this study.

6. Benefits: Are there benefits to taking part in this study?

There may be no direct benefit to you from study participation.

7. Alternatives: What other choices do you have if you do not take part in this study?

You may get clinical audiology testing and a fitting for a hearing aid outside of this study.

8. Confidentiality: Will your medical information be kept private?

Confidential information contained in your medical record may not be given to anyone except to members of the research group and others who must be involved professionally to provide essential medical care. The study sponsor, the St. Elizabeth's Research/Human Subjects Committee (IRB), and state and federal agencies protecting the welfare of the study participants may view study records.

9. Costs: What are the costs for taking part in this study?

If you elect to participate in this study, you will not be charged for participation in the audiological test battery. However, parking may constitute an additional cost.

For the Anesthesia Group, your insurance company may be billed for the additional 20 minutes of anesthesia time.

Although study funds will pay for certain study-related items and services, the hospital may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research, such as a routine audiological assessment ordered by your physician . You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If your insurance does not pay, or pays only a portion of the costs, the hospital may bill you for any unpaid amounts. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff.

10. Compensation: Will you be paid to participate in this research study?

There will be no compensation for participation in this study.

11. In Case of Injury: What happens if you become injured because of taking part in this research study?

There is no anticipation that participation in this study will result in injury.

However, if you become sick or injured by your direct participation in this research study, medical treatment will be provided to you including first aid; emergency treatment and follow-up care as needed. St. Elizabeth's Medical Center will bill your health insurance for the cost of such care. If your insurance does not pay for your care, or pays only a portion of the cost of such care, St. Elizabeth's Medical Center may bill you for any unpaid amounts. No special arrangements will be made for the compensation or for the payment of treatment solely because of your participation in this research study. St. Elizabeth's Medical Center and persons conducting this research study are not admitting fault for your injury or illness by providing or making available medical treatment for your injuries or illness. This paragraph is a statement of the St. Elizabeth's Medical Center policy and it does not give up any of your legal rights.

It is important that you tell the principal investigator/study doctor if you feel that you have been injured because of taking part in this study. If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, you can tell the principal investigator/study doctor in person or call him/her as soon as possible at: (617) 779-6460.

12. New Findings/New Information:

New information might be learned during this study that you should know about. The investigator will tell you about new information that may affect your willingness to stay in this study and you can then decide if you want to continue in this research study. At that time, your consent to continue participation will be required.

13. Number of Subjects:

The number of subjects to be enrolled at St. Elizabeth's Medical Center and SMG Otolaryngology-Brockton will be 2,000.

14. Termination without Consent:

If you are eligible to participate and agree to be in this study, the principal investigator may still choose to stop your participation in the study if he/she thinks it is in your best medical interest. The principal investigator may stop you from taking part in this study at any time if he believes it is in your best interest; if you do not follow the study rules; or if the study is stopped. If this happens, the principal investigator will tell you why.

15. Contacts:

If at any time during this research study, you feel that you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject, have a complaint about the research or feel under duress to participate against your wishes, or to continue with the study, you can contact a member of the Research/Human Subjects Committee (a group of people who review the

research study to protect your rights), who will be available to speak with you during normal working hours (8:30 a.m. to 5:00 p.m.) at:

Institutional Review Board (IRB) Office
Telephone: 617-789-2804
Address: 736 Cambridge Street , Boston, MA 02135

You may also contact the Principal Investigator or Representative at any time during this Research study for questions and answers regarding the Research study at: (617) 779-6460. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

16. HIPAA Authorization to Use and Disclose Protected Health Information for Research Purposes

Purpose: As a research participant, I authorize St. Elizabeth's Medical Center, including its health care providers, researchers, research staff and Institutional Review Board, to use and disclose my individual health information for the purpose of conducting this research project.

My individual health information that may be used or disclosed to conduct this research includes the following:

☒ All information collected during the research study as described in the informed consent.

☐ Health Information to Conduct Research ☐ Complete Records

☐ Laboratory Reports ☐ X-Rays/Images ☐ Physical Therapy

☐ Outpatient Records ☐ Pathology Reports ☐ Emergency Reports

☐ Consult ☐ History & Physical ☐ Discharge Summary

☐ Other Specified:

Restricted Release: By signing next to a category of highly confidential information listed below, I specifically authorize the use and/or disclosure pursuant to this Authorization.

Release	Signature	Release	Signature
☐ Mental/Behavioral Health & Disability Services Provider Documentation*		☐ Genetic Testing/Test Results**	
☐ HIV/AIDS Screening Test Results		☐ Alcohol*** and/or ☐ Substance Abuse Treatment***	
☐ Confidential Communications with a Social Worker		☐ Child/Elder Abuse and Neglect & Abuse of an Adult with a Disability	
☐ Rape/Sexual Assault Victim's Counseling		☐ Domestic Violence Victim's Counseling	
☐ Sexually Transmitted Disease			

* This authorization is not valid for use or disclosure of psychotherapy notes
** The term "genetic tests" means only those tests which determine your future chances of developing a disease, not tests done to diagnose a current condition or problem. This includes information related to the testing of embryo's created during IVF.
*** Only applicable to records that are created by an "individual or entity who holds itself out as providing alcohol or drug abuse diagnosis, treatment or referral for treatment." (42 CFR Part 2) Does not include records created or maintained by a general medical facility.

The persons who are authorized to use and disclose your protected health information are:

☒ Mark A Parker PhD and other members of his research team at St. Elizabeth's Medical Center and SMG Otolaryngology-Brockton who are participating in the conduct of this research study.

☒ The Institutional Review Board (IRB)

☐ Others: _____

The persons who are authorized to receive this information are:

☐ The sponsor of this study: _____ ☐ Others: _____

Federal or other governmental agencies as required for their research oversight and public health reporting in connection with this research study:

☒ Office for Human Research Protections (OHRP) ☐ US Food and Drug Administration (FDA)

☐ National Institutes of Health (NIH) ☐ Other: _____

Right to Refuse to Sign this Authorization: I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any research related treatment that is provided through the study. However, my decision not to sign this Authorization will not affect any other treatment, payment, or eligibility for benefits.

Right to Revoke: I understand that I may revoke this Authorization at any time by sending a written notice to Mark A Parker PhD at 736 Cambridge St, SMC8, Brighton, MA 02135. If you withdraw this Authorization, Mark A Parker PhD and his/her research staff may only use and disclose individual health information already collected for the study. No additional health information about you will be collected by or disclosed to the researcher for the purpose of this study. Revoking this Authorization will not affect your healthcare or your relationship with Mark A Parker PhD or St. Elizabeth's Medical Center.

Potential for Re-disclosure: My individual health information disclosed under this Authorization may be subject to re-disclosure outside this research study and no longer protected by applicable state and federal law once disclosed. For example, researchers in other studies could use my individual health information collected for this study without contacting me, if they get approval from an Institutional Review Board (IRB) and agree to keep my information confidential. I further understand that my health information may be disclosed as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of

medical products and therapies and the conduct of research.

Suspension of Access: I may not be allowed to review the information collected for this study, including information recorded in my medical record, until after the study is completed. When the study is over, I will have the right to access the information again.

Health Information from Other Institutions: I understand that if it is necessary for Mark A Parker PhD to obtain health information/records from other institutions, I will need to complete an additional Authorization to release these records to Mark A Parker PhD.

HIPAA Authorization for Optional Additional Study Procedures:
You must also give us your permission under HIPAA rules to use and disclose the information collected from optional study procedures. If you decline to give us permission to use and disclose your information from these optional procedures, you cannot take part in these optional procedures, but you can still participate in the main study.

Term: This Authorization shall expire upon completion of the study.

Access: I understand that I have the right to access my Protected Health Information, which is maintained by St. Elizabeth's Medical Center, in St. Elizabeth's Medical Center's Designated Record Set, upon completion of the Authorization to Use and Disclose Protected Health Information. I also understand I have the right to view and/or have copied my Protected Health Information in its entirety or an abstract. Based on State and Federal Law, St. Elizabeth's Medical Center has a right to deny me access to all or portions of my Protected Health Information and must notify me in writing. I understand that St. Elizabeth's Medical Center may charge a reasonable cost based fee associated with copying my Protected Health Information. I may contact the Correspondence Department at 617-789-3000.

Statement of Principal Investigator or Person Obtaining Consent

The subject has been informed of the nature and purpose of the procedures including any risks involved in the research study's performance. The subject has been asked if any questions have arisen regarding these procedures and these questions have been answered to the best of the investigator's ability. A signed copy of this informed consent has been provided to the subject.

Also, any new unforeseen information relevant to the patient that may develop during the course of this research activity will be provided to the subject and the Research/Human Subjects Committee (IRB). I will inform any referring physician(s) of any and all protocol changes, adverse events and/or safety reports.

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Statement and Signature of Subject

I have been informed about the procedures, risks, and benefits of this Research Study and agree to participate. I know that I am free to withdraw my consent and to quit the Research Study at any time. My decision not to participate in this Research Study or my decision at any time to withdraw from this Research Study will not cause me any penalty or loss of benefits that I am otherwise entitled to.

I have read or have had this form read to me and understand the terms of this Consent Form and I have had an opportunity to ask questions about the Study and to discuss the Study with my doctor and other health care providers and my family and friends.

I hereby consent to have my medical records relating to this research activity be made available to state and federal agencies (including but not limited to the Department of Health and Human Services' Food and Drug Administration (FDA)), which regulates medical research activity, including this research study. I understand that while every effort will be made to keep my identity confidential, there may be occasions when my identity must be made known to state and federal agencies at their request.

I have read and understand the terms of this Authorization and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize St. Elizabeth's Medical Center to use or disclose my health information in the manner described above. I will receive a copy of this Authorization form after I sign it. I give permission for my individual health information from the optional procedures I have agreed to in the informed consent form to be used and disclosed in the manner described in the informed consent form.

I understand that this research study has been reviewed and approved by the Research/Human Subjects Committee, the Institutional Review Board (IRB) of St. Elizabeth's Medical Center.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Subject's Authorized Representative (if applicable)	Signature of Subject's Authorized Representative	Date	Time

Relationship to subject (indicate authority to act for subject): _____

Printed Name of Witness or Interpreter	Signature of Witness or Interpreter	Date	Time

For Office Use:

☐ Copy of this authorization provided to the patient or personal representative

☐ Copy of this authorization provided to the Steward Covered Entity Medical Records Department