Partners HealthCare System
Research Consent Form

Subject Identification

Parent Template
Version Date: January 2019

Protocol Title: The use of amplification in unilateral hearing loss

Principal Investigator: Michael Cohen, MD

Site Principal Investigator: Michael Cohen, MD

Description of Subject Population: Children ages 6-12 with unilateral hearing loss

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to give permission for your child to take part. If you decide to give permission for your child to take part now, you can change your mind and s/he can drop out later. Your decision won't change the medical care your child gets within Partners now or in the future.

The following key information is to help you decide whether or not to give permission for your child to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about whether a hearing aid can help children with hearing loss in one ear only.

How long will your child take part in this research study?

If you decide to give permission for your child to join this research study, it will take your child about **7 months** to complete the study. During this time, we will ask you to make **2** study visits to **Massachusetts Eye and Ear.**

What will happen if your child takes part in this research study?

If you decide to give permission for your child to join this research study, the following things will happen: **ear mold, hearing aid fitting, hearing aid use, survey completion.**

Why might you choose to have your child take part in this study?

We cannot promise any benefits to your child from taking part in this research study. However, possible benefits may include improved hearing**.** Others with **hearing loss in one ear only** may benefit in the future from what we learn in this study.

Why might you choose NOT to have your child take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include discomfort from wearing a hearing aid.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are **the time it will take to complete the surveys**.

What other treatments or procedures are available for your child's condition?

Other treatments or procedures that are available to treat hearing loss in one ear include not wearing a hearing aid.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Michael Cohen is the person in charge of this research study. You can call him at (617) 573-4250. You can also call **617-573-6060 during normal business hours** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **617-573-6060 during normal business hours.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

You and your child are invited to take part in a research study designed to see whether a hearing aid is helpful for children with hearing loss in one ear (unilateral hearing loss).
Your child has been asked to take part in this study because he/she has unilateral hearing loss. Unilateral hearing loss affects approximately 3-5% of school-aged children.

We will compare the use of standard accommodations for children with unilateral hearing loss to those same accommodations plus the use of a hearing aid. Standard accommodations include use of an FM (frequency modulated) system and preferential seating in school. An FM system amplifies the teacher's voice by sending sounds from a microphone worn by your child's teacher to an earpiece worn by your child. An FM system is different from a hearing aid as it only amplifies the teacher's voice, while a hearing aid amplifies all sounds in the room. Currently, we do not know whether use of a hearing aid in addition to an FM system helps, hurts, or makes no difference for children with unilateral hearing loss.

The hearing aid used in the study is FDA-approved and used by many individuals with bilateral hearing loss, but not unilateral hearing loss. The hearing aid will be used for the purpose of this research study only.

If your doctor is also the person responsible for this research study, please note that he/she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Who will take part in this research?

This study is being conducted by Dr. Michael Cohen at Massachusetts Eye and Ear Infirmary. The study is also being conducted at other sites, including Boston Children's Hospital, Cleveland Clinic, and Emory University. This study involves your child wearing a hearing aid while child at school and at home and also having the child, parent, and a teacher complete surveys.

What will happen in this research study?

About 100 children will take part in this research study at Mass. Eye and Ear, Boston Children's Hospital, and Cleveland Clinic. You are being approached to have your child participate in this study because your child has unilateral hearing loss.

In this study, the child will be asked to compare standard classroom accommodations (including use of an FM system and preferential seating) to these same accommodations plus the use of a hearing aid. He/she will use each of these strategies for a three-month period, totaling six months for the entire study, completing quality of life surveys at regular intervals throughout the study. The student will be randomly chosen to use the hearing aid either during the first three-month time-block or during the second three-month time-block. Each block will be separated by a two-week interval. In addition to the student evaluating their own quality of life, we ask that evaluations be completed by you (the child's parent), and by his/her teacher.

The surveys that are to be administered ask questions regarding hearing difficulty in particular situations, such as in the classroom or in noisy situations. In addition, they will ask how much the hearing loss affects your child socially. Surveys for you and your child that are to be answered in between visits (i.e. 6-week mark) will be administered via email through a secure data collection tool known as REDCap (Research Electronic Data Capture). Those that are given at the beginning and end of each 3-month period will be given at the clinic visit. All teacher surveys will be administered via email through REDCap. In addition, contact by phone or email will be made at the 6-week mark in each arm (when a survey is due to be filled out).
It will take you about **7** months to complete this research study. During this time, we will ask you to make **4** study visits. Each visit will take about **1** hour

How may we use and share your child's samples and health information for other research?

The samples and information we collect in this study may help advance other research. If your child joins this study, we may remove all information that identifies your child (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to your child. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You and your child's doctor should not expect to get information about the results of the research study or the results of your child's individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your child's health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your child's health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

Your child may find the hearing aid uncomfortable to wear. In addition, your child may not like the way it looks or feel teased by classmates in school. Your child may not notice any benefit from the hearing aid or they may find it to be distracting.

There is a small chance that information from this study could become known to others. We have protections in place to prevent this from happening. All study participants will be identified by a code number which will be allow study information to be kept separate from protected information such as name and date of birth. We will keep the list of code numbers separate from other information collected in this study in a secure manner. We use password protected computers and limit who has access to the information we obtain for this study. In addition, sending survey responses by email carries the risk of information becoming known to others as well. The use of REDCap, a secure research database system, will minimize this risk.

You will be informed of significant new findings developed during the course of this research study which may relate to your child's willingness to continue participation.

Participation in this study may involve risks that are currently not known.

What are the possible benefits from being in this research study?

Your child may notice improvement in hearing and may find it easier to concentrate at school. Your child may also notice that it is easier to distinguish sounds in a loud environment. Your child will also be helping to improve our understanding of what treatments work best for children with unilateral hearing loss. However, your child may have no direct benefit from taking part in this research study.

What other treatments or procedures are available for your child's condition?

If you and/or your child decide not to participate in the study, your child will continue using standard accommodations as they are currently being used.

Can your child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and your child won't lose any benefits your child receives now or has a right to receive.

We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should you do if you want your child to stop taking part in the study?

If your child takes part in this research study, and you want him/her to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask your child to drop out of the study before s/he finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

Will you or your child be paid to take part in this research study?

There will be no monetary compensation for participation in the study. At the end of the study, if your child chooses, he/she may keep the hearing aid for personal use if he/she feels there is benefit from its use.

We may use your child's samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you or your child if your samples or information are used for this purpose.

What will you have to pay for if your child takes part in this research study?

You will still be responsible for any co-pays required by your insurance company for standard treatment. There are no research-related costs for which you will be responsible.

What happens if your child is injured as a result of taking part in this research study?

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for the injury aside from what was described above. However, you are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the researcher in charge of the study as soon as possible. The researcher's name and phone number are listed on this consent form.
Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If your child takes part in this research study, how will we protect your child's privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to your child or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your child's identifiable information might not have to follow the same privacy rules that we follow and might use or share your child's identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's identifiable information only when we must, and we ask anyone who

receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact you or your child without your permission and will not use or share your child's identifiable information for any mailing or marketing list. However, once your child's identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's identifiable information. Your permission to use and share your child's identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's identifiable information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your child's identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- **I have explained the research to the study subject.**
- **I have answered all questions about this research study to the best of my ability.**

Study Doctor or Person Obtaining Consent	**Date**	**Time (optional)**

Consent Form Version Date: 24 July 2019