CONSENT/PERMISSION/ASSENT and HIPAA AUTHORIZATION

For adult participants, parents/guardians, and youth ages 11 and older

To participate in a research project titled

Audiological Management of Children with Unilateral Hearing Loss

This form shows that

Participant's First Name Middle Name Last Name *(optional)* **Date of Birth**

agrees to participate in a research study with Boys Town National Research Hospital.

In the sections that follow, the word "we" means the study investigator and other research staff. If you are a parent or legal guardian who is giving permission for a child/dependent, please note that the word "you" refers to your child/dependent.

What is this research study about?

We are doing a research study about ways to help children who have hearing loss in one ear.

We hope to learn how hearing experiences affect children's ability to tell where sounds come from, use language, and do well in school.

Before you decide if you want to join, we will discuss what the research is for and how you would be involved. We will also discuss how your research data and your private health information are protected and shared. Please stop and ask if you want something explained to you.

Am I required to be in this study?

Your participation in this study is completely voluntary. You do not have to join. If you decide to join, you can still quit the study at any time. No matter what, Boys Town will not change the way we treat you and your family.

If you decide to quit the study, please contact Ryan McCreery at Ryan.McCreery@boystown.org.

What will happen if I decide to be in this study?

Protocol: 26-030
Approved: 08/18/2026
Expires: 08/17/2027

You will be asked to complete some standard clinical tests, including brain scans, and fill out surveys. This study could take up to 4 hours per visit and can be completed over multiple visits. You will be asked to complete some of the tests and surveys every year after you start the study for up to 3 years.

Otoscopy

- An otoscope is the size of a small flashlight. It is used to look into your ear canal. It will not cause you any discomfort.
- This exam typically takes less than a minute. There are no known risks from this exam.

Acoustic Immittance or Tympanometry

- Tympanometry tests how well your middle ear works. A small earplug will be placed into each ear. You will hear a low-pitched sound and feel pressure in your ear. Sometimes a loud sound is also presented.
- This tests a small muscle in the middle ear. The sound is not loud enough to damage your hearing. You may notice slight discomfort from the earplug.
- Testing takes 3-5 minutes. There are no known risks from taking this test.

Probe Microphone Testing

- This test measures how loud your hearing aid(s) are. A small and flexible tube with a microphone is placed into your ear canal. Some find the tube to be uncomfortable.
- You will hear a series of sounds. The sounds will not be loud enough to damage your hearing. All you have to do is sit quietly during the test, which should take 5-15 minutes. There are no known risks from taking this test.

Hearing Testing

- The hearing tests measure how well you hear.
- You will hear a series of sounds presented over earphones and indicate when you hear them or when they sound different from others. You may be asked to play a game to tell the tester when you hear the sounds.
- This test will take about 10-60 minutes. There are no known risks from taking this test.

Parent/Guardian Questionnaires

- Your parent/guardian will complete surveys about your attention, behavior, and memory skills at home; how often you wear your hearing aids at school and at home; how you hear and listen in different settings; and your speech and language history.
- Your parent/guardian may be asked for some health, medical, and social information about themselves, you, and your family. They may be asked about how you use language in different situations.
- These surveys should take 15-30 minutes.

Self-Questionnaires

- You may fill out a survey about how you hear at school, how you hear speech sounds, and how easy or hard it is to listen with or without hearing devices.
- You may be asked to complete a questionnaire that asks you what you think or how you feel about different things. For example, "When I have difficulty hearing my friends, I feel frustrated."
- You may be asked how your hearing devices and remote microphone system are working at school.
- You may be asked to rate how new hearing devices look and sound.
- There is a small risk of fatigue or frustration when completing questionnaires. To reduce fatigue and/or frustration when completing questionnaires, you will be encouraged to take breaks as needed. You may also complete the questionnaires across multiple sessions if you prefer.
- These surveys should take 5-30 minutes.

Speech Language Testing

- These tests measure:
    - How you talk (speech).
    - How you understand words and sentences, and how you recall details from stories you read and/or hear (speech and language).
    - How you pay attention (executive function).
    - How you remember what is seen and heard (working memory).
    - How you solve problems based on visual or auditory patterns (problem-solving).
- You will see and point to pictures in a book or on a computer. You may be asked to break whole words into smaller pieces or imitate made-up words. You may play a game while background noise is playing. You may solve a series of puzzles.

- These procedures may take 1 to 2 hours.

Magnetoencephalography (MEG)

- MEG is a tool that records brain activity using a helmet that looks like an old-time hair dryer. MEG is completely harmless and cannot hurt you.

- We can record your brain activity while you are doing a cognitive task or while you're awake and not doing anything. You will need to hold very still for each recording, but you will be offered breaks between tasks, about every 5 to 20 minutes.

- Prior to the MEG scan, we will tape several sensors to your head. We use these sensors to monitor your eye movements, head position, and heartbeat; they do not do anything to you and are simply monitoring devices. We will then seat you in a special chair, and we will raise the chair slightly to position your head inside the MEG helmet.

- You will participate in simple tasks including listening to sounds, watching pictures, making choices by pressing buttons, or receiving gentle pulse stimulation on the forearm. We may also ask you to relax with your eyes open or closed.

- There will be breaks between the different tasks, and you will be able to be in contact with staff members at all times via video or audio feeds.

- When the scan is over, we will remove all the sensors. The entire scan will take about 60 to 80 minutes, which may be completed in one or two visits, and will be administered by study staff that have had extensive training in MEG data collection.

Magnetic Resonance Imaging (MRI)

- You will also undergo a brain scan called MRI. This scan uses a strong magnet to create a 3D picture of your brain and shows us where your brain is active during tasks or while you are resting. The MRI is also harmless.

- This scan takes about 45 to 60 minutes, with breaks in between different tasks every 5 to 10 minutes.

- During the MRI scan, you will lie down on a table which will go into a long donut-shaped tube. During the scan, you will hear loud banging and knocking noises coming from the magnet. In order to obtain good pictures, it is important for you to stay still during the scan.

- You will be able to talk with the technician during breaks or in case of emergency by pressing a call button or similar device, and you will be able to be in contact with staff members at all times via video or audio feeds. The scan will be done by study staff who are trained in MRI safety.

Will I be paid for this study?

- For study sessions that do **not** involve MEG or MRI: You will be paid $25 per hour for testing.
- For study sessions that involve MEG or MRI: You will be paid $50 per MEG portion and $50 per MRI portion of the study (up to $100).
- It is important to know that payment for participation in a study is taxable income.
- Boys Town is required by law to issue a tax form to any individual to whom it made payments, totaling or exceeding $2,000 during a calendar year. You must be able to provide your name, address, and taxpayer identification number if this occurs. We may ask to collect this information if you are approaching this amount or it is likely you will reach it by the end of the year. We will only provide your information to the IRS if required. When making the required report, we will not reveal the reason for payment, nor any information about the study in which you are participating.

Research Participant Agreement: Taking part in this study will not make you an employee of Boys Town.

What should I do if I might have an injury from participating in this study?

We use safe procedures, and the chance of injury is small. If you are injured, we will make sure you receive emergency treatment at no cost to you. If you take part in this study somewhere outside of Boys Town, that organization will treat you according to its own policies.

What are the possible problems, discomforts or risks?

Audiology and Speech Language Testing

- None of the sounds will be loud enough to cause discomfort or damage hearing.
- You may experience slight discomfort from the earplugs we place in your ear canal to play sounds or measure immittance/tympanometry. This discomfort should go away when the earplug is removed from your ear canal.
- There is a small risk of fatigue, eye strain, and/or frustration when completing visual tasks and/or questionnaires.

- If an audiologist has to remove earwax, it could cause a small scrape on the skin of your ear canal. There is also a small chance your ear canal could become infection, or your eardrum could be injured.
- At times, the tasks may seem boring or make you feel tired. We will offer frequent breaks to reduce this risk.

MEG/MRI

There are risks of stress and frustration if you cannot remain still in the MEG or MRI environment or cannot complete the cognitive tests. We generally recommend rescheduling the session before you get frustrated to eliminate this risk.

- **MEG:**

You may have some skin irritation or accidental hair removal from the tape used to attach the coils/sensors for the MEG portion of the study. Most people do not experience physical or emotional discomfort with the MEG; however, it is possible that you will experience discomfort.

Participation in this study may produce feelings of emotional stress, inconvenience, or an invasion of privacy. We will make every effort to protect the information you give us. However, there is a small risk of loss of confidentiality. Procedures we will use to protect the information you give us are described in the sections below.

It is possible that other rare side effects could occur which are not described in this form. It is also possible that you could have a side effect that has not occurred before.

- **MRI:**

Radio and magnetic waves associated with MRI scans are not associated with any known negative effects. MRI is non-invasive and considered minimal risk by the FDA.

However, the scanner is a large magnet, so it can move objects metallic objects. This means that loose metal objects, like coins or key chains, are not allowed in the MRI room. If you have a piece of metal in your body such as a nerve stimulator, piercings, or certain metal surgical implants, we will not allow you into the MRI room or have an MRI.

While in the scanner, you may be bothered by feelings of claustrophobia (fear of small spaces). If you feel uncomfortable in the MRI scanner, you should tell the research staff. The MRI also makes loud 'drum' beating noises during the study. We will provide ear plugs for your comfort.

There is a speaker in the MRI scanner room as well as a window that allows the operator to view you during your brain scan. This allows us to always hear and see you. We will ensure that you are comfortable and will respond if you are uncomfortable. You can stop the scan at any time.

Could being in this study benefit me?

- The reason for this study is to help us find ways to improve speech and language processing for children who are hard-of-hearing. Improved processing skills may help them do well in school.
- As part of this project, you may receive hearing, speech, and/or language tests at no cost.
- Removal of earwax may result in better hearing.

What information will you collect?

- There are different kinds of information that we collect during a research study, such as how to contact you or your protected health information, also called "PHI".
- We will need PHI about you that may reveal who you are. This includes things learned from the procedures described in this consent form. We may also collect other information such as your contact information or information from your medical records, but only as described in this form.
- Signing this form means you are giving us permission, called your "authorization," to use and share PHI protected by the Privacy Rule.
- It is your choice whether you share your PHI. If you decide not to give us permission, you may not take part in this study.
- We will gather PHI about you, such as your Name, Address, Dates such as date of birth or date of hearing loss diagnosis, Telephone numbers, Email addresses, Medical record numbers, and biometric identifiers such as audio recordings.

How is my information protected?

- We do everything we can to keep your information private, although there is always a chance someone could find out your information is from you.
- We will not reveal your identity unless it is required by law.
- We will not use your real name if we publish or present the results from this study.
- Boys Town has rules to protect information about you, including our Notice of Privacy Practices. Federal laws, such as the Privacy Rule, and state laws also protect your privacy. These laws require that we get your permission to use or share your protected health information, also called "PHI."
- We will give you an ID number so that your data is not kept with your name. We will keep your data in locked cabinets and secure servers.

- The National Institutes for Health funded this research and issued a Certificate of Confidentiality to further protect your privacy. This means that researchers cannot release or use information that may identify you in any legal action unless you say it is okay. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court order. The Certificate DOES NOT stop reporting required by law, such as possible child abuse, communicable disease, or threats to harm yourself or others. It does not prevent your information from being used for other research if approved by an Institutional Review Board, which reviews and approves research studies. It also does not prevent you from sharing your information with others or giving permission to researchers to share your information.

Who can see my information?

We may add research information about you to a secure database to use for this study. This information may be accessed by other researchers at Boys Town. We may also use the information to contact you in the future about other studies to take part in, but it does not mean you have to join in other studies. We may also use the information for future research studies without contacting you, but only with permission by Boys Town's Institutional Review Board (a committee that oversees research studies).

With your permission, we may also use the information to contact you in the future about other studies to take part in. This does not mean you have to join in other studies.

_____ I agree to be contacted about future studies.

_____ I DO NOT agree to be contacted about future studies.

- For the most part, only the researchers on this study will see your information. However, we might be required to share your PHI with the following people:
  - Other people at Boys Town, for reasons like study oversight, payment, or clinical care.
  - Other sites in this study, or the companies or agencies that sponsor the study.
  - Public Health authorities who regulate research (such as the Office of Human Research Protection or the Food and Drug Administration).
- We will try to make sure that everyone who needs your PHI keeps it private. However, if we share your information with others outside of Boys Town, such as the sponsor of the study or a government regulatory agency, we cannot guarantee that those people will protect your information.
- We may continue to use and share your PHI for up to 3 years after the end of the study.

- You can cancel your permission allowing us to use and share your PHI at any time by writing to Ryan McCreery (Ryan.McCreery@boystown.org). Once you cancel your permission, you will not be in the study, and we will stop collecting PHI about you. We may have already collected some PHI about you. We may continue to use and share that PHI for this study.

Who should I contact if I have questions?

If you have any questions about the research, contact the researcher responsible for this research:

Ryan McCreery, Ph.D., Director of Research
Boys Town National Research Hospital
555 N 30th St, Omaha, NE 68131
531-355-6668
Ryan.McCreery@boystown.org

IRB Contact Information: If you would like to talk with someone about your rights as a participant in this research study or about ethical issues with this research study, please contact the Boys Town Institutional Review Board by email at IRB@boystown.org.

We are required by law to provide you with a signed copy of this form. It contains valuable information about the study and your rights as a study participant.

You will receive an electronic copy of this signed form sent to an email address that you provide. It will be a "PDF" document. If you are unable to open the "PDF" document, or you would prefer to receive a paper copy at no cost to you, please contact the researcher listed above.

Statement of Consent and Authorization to use my Data:

- **I have the legal authority to sign this form.**
- **I have discussed the above information with the researchers.**
- **All of my questions have been answered.**
- **I give permission for the researchers to use and share my PHI as described in this form.**
- **I voluntarily agree to take part in the study.**

Participant Signature (ages 11+) **Date**

Parent/Guardian/Legally Authorized Representative (LAR) Signature **Date**

Printed Name of LAR **Relationship to Participant**

Researcher's Statement: I have discussed with this participant the procedure(s) described above, and the risk involved. I believe this participant understands the content of the consent form and is competent to give legally effective and informed consent.

Signature of Person Obtaining Consent **Print Name** **Date**

For Phone Consent Only: I witnessed the phone call between the researcher and this participant reviewing the procedure(s) described above and the risk involved. I believe they understand the content of the consent form and are competent to give legally effective and informed consent.

Witness' Signature **Print Name** **Date**