

**Affix Patient Label Here**

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:**MRN:**

Parent Permission for a Child to Participate in a Research Study

Study Name: Neural Prediction to Enhance Language Outcomes in Children with Cochlear Implant [Treatment Arm]

Sponsored by: National Institutes of Health (NIH)

Name of Researcher (referred to as the study doctor): Dr. Nancy Young

This consent form describes a research study for which your child might qualify at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") and Northwestern University (NU). Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care.

What are the purpose and goals of this study?

The purpose of this study is to see how different children develop spoken language following cochlear implantation. We are interested in looking at brain scans obtained before cochlear implant surgery. Our goal is to predict which children will need more therapy and to understand what type and amount of therapy would be most effective for each child based on their brain structure.

We expect to enroll about 40 children into the study who will receive parent child communication intervention therapy for six months. We also hope to enroll 160 children who will not receive the communication intervention therapy.

If I agree to have my child take part in this study, what would my child and I need to do?

If you agree to have your child take part in this study, researchers will review your child's medical records including their general health history, history related to hearing loss, MRI scans, surgical reports, and hearing and language evaluations done before and after cochlear implant surgery.

Taking part in the study also involves your child undergoing a speech and language evaluation for research purposes each year for up to five years. This evaluation will take less than two hours. It will take place at a Lurie Children's outpatient center, the main hospital or the Northwestern University Department of Communication Sciences and Disorders. The speech and language evaluation will be conducted by trained professionals from Northwestern University.

Your child's medical records will be reviewed periodically during the study. Information that will be shared with our collaborators at the Chinese University of Hong Kong (CUHK) will include your child's birth date and date he/she received cochlear implant services at Lurie Children's. Your child's name and medical record number will not be shared. We will study your child's progress for up to five years after their first cochlear implant is turned on.



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

We will ask you to complete surveys about your socio-economic and education background, personal and family history of communication and your child's communication ability. We will also ask you to complete surveys each year about your child's reasoning and understanding and the overall progress your child has made since receiving a cochlear implant. These surveys can be completed online during your child's visit to the audiology department. If you are unable to complete the survey during the visit, a link will be sent to you by email so that you may complete it from home. Information from these surveys will be maintained confidentially.

You and your child will receive weekly one-hour intervention sessions over video call (Zoom) for 6 months (26 sessions). This therapy will be conducted by trained professionals in Megan Roberts, PhD's research group at Northwestern University. All therapy sessions will be video recorded. During each session a professional will work on increasing your child's social communication by providing strategies for you to use to help your child learn language during your usual every day activities. This means that you will be at every session and your child will never interact directly with the clinician or the video screen. Instead, the therapist will watch you playing with your child and provide live feedback and coaching about how to incorporate language strategies as you play with your child or do everyday activities. Other family members can observe, but they will not be able to participate in the session.

The therapy intervention used in this study has been shown to be successful in helping children with hearing loss to develop language. Other therapy services your child is receiving should continue during the six months of these weekly sessions. The therapy provided during this part of the study will be in addition to your child's other services.

Another member of Dr. Roberts research team will evaluate the way you and your child interact together. This evaluation will take place over video call (Zoom) and will take 12 minutes. It will be done every month during the six months of therapy and again at a year and two years after your child began using the implant.

What are the risks, side effects, or discomforts related to the study?

There are no obvious serious risks for you and your child to participate. If your child becomes uncomfortable or tired during any of the therapy sessions or evaluations, we will offer a break and the assessment can be stopped at any time.

The only potential risk to participating is the risk of confidentiality being broken. To help protect your privacy, we will assign your child a unique study identification number and keep your study information in a password protected database or computer server.

As a part of downloading and using the video software (Zoom), personal data may be collected by the video service. Videos recorded will be immediately saved to a secure drive after which the recording on Zoom will be deleted.

There is a risk in allowing access to your child's hospital medical records. This study has taken precautions to decrease these risks. Any individually identifying information, such as birth date,



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

date of service and research-only videos will be shared with our collaborators by encrypted electronic file sharing to ensure privacy.

Data will be kept on a password protected computer or in a locked cabinet in a secure location with restricted access. Videos of your child will be stored in a secure location on a server at Northwestern University and at Lurie Children's and not shared with collaborators at the Chinese University of Hong Kong.

The research team may also use a HIPPA compliant texting platform to send you text reminders about upcoming appointments and surveys that need to be completed.

If it is best for your child, the study doctor may decide to take your child out of the study.

What are the benefits from this study?

The information learned from this study may help other children who receive a cochlear implant in the future. It is possible that your child will benefit from the additional therapy received by developing better language.

What other options does my child have?

You have the option to choose not to take part in this study or in the *Optional Component*. Choosing not to participate will not affect your medical care or the medical care of your child. If you withdraw your child from this study, it will not affect your medical care or the medical care of your child.

What if my child's study doctor or I do not think my child should stay in the study?

Your child can stop taking part in this study at any time. Your choice will not affect your child's regular care.

Returning Study Results:

The study team will not return study results to you and your child. You can ask the study team any questions you have about study results.

Important New Information:

We will tell you if we learn new information that may make you change your mind about your child being in this study.

Planned Sharing of your Child's Information:

If you agree to let your child take part in this study, you also give permission to the use and sharing of your child's information. This permission lasts until the study is completed.

This information that may be collected and shared will include your child's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

The study staff, employees, and Medical Staff of Lurie Children's and Northwestern University (NU) may use your child's information and share it with:

- The study sponsor, NIH, and those working with the sponsor.
- Chinese University of Hong Kong (CUHK)
- Northwestern University (NU)
- Other participating sites
- The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your child's other providers and their staff directly involved in your child's care, if your child's provider is a part of the Lurie Children's electronic health information exchange.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people to which we will give your child's information. We cannot guarantee that those listed above will not share it with others without your permission.

Your child's name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my child's information?

If you decide not to allow the release your child's information, your child will not be able to take part in this study. If you give permission to the use of your child's information, you can withdraw it at any time. Your request should be in writing and sent to the study doctor. The study team can still use any information collected before you tell them to stop.

Can I review or copy my child's information?

You can review and have a right to request a copy of your child's medical record. You cannot see the results of evaluation done only for research purposes only as part of this study. Evaluations done for research purposes only will not be stored in your child's medical record. These evaluations include the study surveys you will be asked to complete and any optional components of the research, described below, in which you agree to participate.

Will my child's information or samples be used in future research studies?

Your child's information or samples collected for this study will not be used for future research, even if identifiers are removed.

Costs Related to this Study:

The study sponsor will pay for all study related costs.

Payment for Taking Part in this Study:

You will be given or mailed an electronic gift card to receive compensation for participation. The card will be loaded with \$20 after you complete the initial surveys about your child's development, your socio-economic and education background, and your child's and family's history of communication. Furthermore, this card will also be used to give you \$20 for completing the yearly surveys about your child and the progress you have observed. After your child completes the



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

annual face to face speech and language evaluation, the card will be used to give you \$40. After your child completes the parent child intervention therapy program you will receive \$100.

Your and Your Child's Rights When Taking Part in this Study:

If you agree to have your child take part in this study, you are not giving up any of your or your child's legal rights. Your child can stop participating in this study at any time. Your choice will not affect your child's regular care.

Who can answer my questions about this study?

If you or your child has any questions, contact the study doctor, Dr. Nancy M. Young, by calling (312) 227-6812 during a workday or (312) 227-4000 at night or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

You will be given a copy of this consent form. A copy will also be placed in your child's medical record.

Optional Research 1: Additional MRI Scan before Surgery

Your child can still take part in the study if you do not agree to the optional research described below.

What are the purpose and procedures of this optional research?

The purpose of this optional component is to obtain additional information about the brain structure of children with hearing loss who receive a cochlear implant. The researchers wish to learn if this additional information about the brain can be used to predict hearing and spoken language development after cochlear implantation.

The additional MRI scans of the brain will be done while your child is under general anesthesia in the Lurie Children's Department of Medical Imaging for his or her MRI scan of the brain and ears that is routinely done before cochlear implantation. The additional research-only scanning will add about 20 minutes, bringing your child's total MRI scan time to about 60 to 80 minutes. The addition of approximately 20 minutes to complete your child's scanning does not significantly change the dose and risk of anesthesia.

What are the risks, side effects, or discomforts related to the optional research?

If you choose to participate in the *Optional Component 1: Additional MRI Scan Before Surgery*, the additional risks to your child will be minimal. The optional scanning will be done while your child is under general anesthesia for his or her MRI scan of the brain and ears that is routinely done before cochlear implantation. The optional scanning is estimated to take an additional 20 minutes during which your child will remain sedated.



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

The risks of the optional scanning are the same as those for your child's standard MRI scan before cochlear implant surgery. These risks include problems if metal objects are brought into the MRI room and sleepiness for several hours after the sedation is given, temporary slowed or difficult breathing or lowered blood pressure from anesthesia. Your child will be constantly monitored by medical staff to minimize risks of sedation.

Many safety measures are in place to reduce risks from movement or heating of metal objects in the MRI room or inside of the body. The staff will screen all persons and materials entering the scanning room for metal and the door to the scanning room will be closed to minimize someone accidentally bringing a metal object inside of the scanner room. Your child should not wear any metal, such as jewelry or clothing with zippers or snaps. As part of the scheduling process, you will be asked if your child wears braces or has any implants.

What information or samples will be kept for this optional research?

All the brain scan data obtained from the optional research will be coded and stored so that your child cannot be identified, except by researchers who have access to the identification codes.

Who will have access to my child's information or samples for this optional research and how will it be kept private?

The research-only imaging data will be shared by Lurie Children's and CUHK study personnel. The research-only imaging data will not contain any information that permits identification of your child. A unique study number will permit the researchers in this study to associate the imaging information with other information from the medical record that you have agreed to share.

Can I take back (withdraw) my permission for this optional research?

You can withdraw your permission to participate at any time. Your request should be in writing and sent to the study doctor. The study team can still use any information collected before you request to stop participation.

Please **initial** next to your choice below regarding the optional testing:

	YES – I agree to allow my child to participate in <i>Optional Component 1</i> .
Initials	

	NO – I do not agree to allow my child to participate in <i>Optional Component 1</i> .
Initials	

Printed Name of Child:



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

Signatures:

Parent/LAR Signature:

By signing this form, I affirm:

- 1) I have read this form.
- 2) The research has been explained to me.
- 3) All of my questions have been answered. I give my consent for my child to take part in this research study.

Signature of Parent or Legally Authorized Representative (LAR):

Date:

Printed Name:

Relationship to Child:

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.

Signature:

Date:

Printed Name:

Signature of Interpreter/Witness*:

☐

Not applicable, no interpreter used.

I attest that the study information has been presented to the parent/legally authorized representative (LAR) in his/her native language. He/she was given the opportunity to have all questions answered.

Signature of Interpreter/Witness:

Printed Name or Unique Phone ID/Company Name:



Affix Patient Label Here

Note: Label required for cover page, but is optional for other pages if the following information is provided:

Patient Name:

MRN:

Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated “short form” (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

- a. The consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*
- b. The parent/LAR should sign the short form (in the language they understand).*
- c. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*
- d. A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.*