Hi, my name is XXX. I work at [The Ohio State University or Nationwide Children's Hospital]. Right now we are trying to better understand how people hear different sounds. We would like to ask you to help by being in a study, but before I do, I want to tell you what will happen if you choose to help me.

You will sit in this big, comfortable chair and watch a movie, or play with an iPad. But you will not hear the sound of the movie or the iPad. You will hear some sounds that are played to your ear, but you do not need to pay attention to the sounds that you will hear. You might have medical stickers placed on your face and head. These do not hurt, but are just stickers that help us know what your brain is doing. If you need to take a break anytime, just tell us. In one part of the study, you may be asked to tell us whether a sound is too loud, repeat some words or sentence you hear, or to pick out a sound that is different to you. Remember, you can ask for a break at any time. There are no right or wrong answers to any of the activities.

When I tell other people about my study, I will not use your name and no one will be able to tell who I am talking about.

Your [mom/dad] says it is okay for you to be in my study. But if you don't want to be in the study, you don't have to be. What you decide won't make any difference in the care you receive at our doctor's office. I won't be upset, and no one else will be upset, if you don't want to be in the study. If you want to be in the study now but change your mind later, that is okay.

You can ask me any questions you have about the study. If you have a question later that you don't think of now, you can call me or ask your parents to call me or send me an email.

Do you have any questions for me now?

Would you like to be in my study?

NOTES TO RESEARCHER: The child should answer "Yes" or "No." Only a definite "Yes" may be taken as assent to participate.

Name of Child: _____ **Parental Permission on File:**
☐ Yes ☐ No

(If "No," do not proceed with assent or research procedures.)

Child's Voluntary Response to Participation: ☐ Yes ☐ No

Signature of Researcher: _____ **Date:** _____

(Optional) Signature of Child: _____

The Ohio State University and Nationwide Children's Hospital
Assent to Participate in Research

Study Title: **Auditory Function in Children**

Principal Investigator: **Shuman He**

Sponsor: **National Institutes of Health**

- **You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.**
- **This form will tell you about the study to help you decide whether or not you want to participate.**
- **You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.**
- **It is okay to say "No" if you don't want to be in the study. If you say "Yes" you can change your mind and quit being in the study at any time without getting in trouble.**
- **If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.**

1. What is this study about?

The purpose of this study is to learn about what responses or reactions people have when hearing different sounds. How well human listeners can encode (change environmental sounds into meaningful hearing information that can be understood by listeners) and understand different sounds is not well understood. A better understanding of this will allow us to provide better care for people with hearing loss.

2. What will I need to do if I am in this study?

In one part of this study, you will either sit in a comfortable chair and watch a silent movie, or play with an iPad. You do not need to pay attention to the sounds that you will hear for this part of the study. You may have medical stickers placed on your face and head. These do not hurt, but are just stickers that help us know what your brain or your nerves are doing. If you need a break anytime, just tell us.
In the second part of this study, you will sit in a comfortable chair. You may be asked to tell us whether the sound is too loud, repeat some words or sentences you hear, or to select a sound that sounds different to you. If you need a break anytime, just tell us.

3. How long will I be in the study?

You may choose which tests to participate in from the assigned testing designated by the research team. You may participate in up to 5 tests. Each test session will take between 1 and 3 hours to complete. Testing may be completed over multiple visits.

4. Can I stop being in the study?

You may stop being in the study at any time.

5. What bad things might happen to me if I am in the study?

We do not expect any bad things will happen to you while in this study. However, things may happen that the researchers do not know about. Tell the researcher or your parent if you feel uncomfortable and we will stop the test immediately.

6. What good things might happen to me if I am in the study?

You will not benefit from being in this study but we might learn something that could help doctors treat people with hearing loss.

7. Will I be given anything for being in this study?

You will be paid to be in this study.

8. Who can I talk to about the study?

For questions about the study you may contact any of the following individuals:

- Dr. Shuman He at 614-293-5963

To discuss other study-related questions with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Signing the assent form

I have read (or someone has read to me) this form. I have had a chance to ask questions before making up my mind. I want to be in this research study.

Signature or printed name of subject	**Date and time** **AM/PM**

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining assent	**Signature of person obtaining assent**
	Date and time **AM/PM**

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.

The Ohio State University and Nationwide Children's Hospital
Parental Permission
For Child's Participation in Research

Study Title: **Auditory Function in Children**

Principal Investigator: **Shuman He**

Sponsor: **National Institutes of Health**

- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.
- **Your child's participation is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University or Nationwide Children's Hospital. If you or your child is a student or employee at Ohio State (OSU) or Nationwide Children's Hospital (NCH) your decision will not affect your grades or employment status.
- **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to learn about what responses or reactions people have when hearing different sounds. Currently, how well human listeners can encode (convert environmental sounds into meaningful hearing information that can be understood by

listeners) and understand different sounds is not well understood. A better understanding of this will allow us to provide the best care for people with hearing loss. This study is designed to address this knowledge gap.

2. How many people will take part in this study?

Overall, 390 participants will take part in this study.

3. What will happen if my child takes part in this study?

We will ask your child to take part in up to 6 listening and/or behavioral tests.

- Each test measures a different area of the hearing system.
- Some tests compare what was heard by your child (psychophysical) to how your child's hearing system reacted.
- We are asking your child to take part in the tests below that have been checked by the researcher.
- We will ask you to write your initials after each test description that is checked, if you agree to let your child participate in that test.

□ **Cortically evoked auditory potentials without a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your child's scalp.
- We will also place foam-tipped earphones in your child's ears.
- Your child will sit quietly in a comfortable chair and watch a silent movie.
- It is important that your child sit still and relax while they watch the movie, but that they do not fall asleep.
- Although your child will be watching a silent movie, they will hear sounds in their ears. Your child can ignore these sounds.
- We will test up to 3 stimulation conditions.
- It will take up to 3 hours to finish each stimulation condition.

_____ *(Initials)* Yes, I give permission for my child to participate in the cortically evoked auditory potentials test.

□ **Cortically evoked auditory potentials with a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your child's scalp.
- Your child will sit quietly in a comfortable chair and watch a silent movie.
- It is important that your child sit still and relax while they watch the movie, but that they do not fall asleep.
- Although your child will be watching a silent movie, they will hear sounds in their ears through the cochlear implant. Your child can ignore these sounds.
- We will test up to 4 types of sounds.
- It will take up to 3 hours to test each type of sound.

_____ *(Initials)* Yes, I give permission for my child to participate in the cortically evoked

auditory potentials section.

☐ **Auditory brainstem response without a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your child's scalp.
- We will also place foam-tipped earphones in your child's ears.
- Your child will sit quietly in a comfortable chair and try to fall asleep if it is possible.
- It is important that your child sit still if they cannot fall asleep during the testing.
- Your child will hear sounds in their ears. They can ignore these sounds.
- This test will take up to two hours.

_____ *(Initials)* Yes, I give permission for my child to participate in the auditory brainstem response section.

☐ **Auditory brainstem responses with a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your child's scalp.
- Your child will sit quietly in a comfortable chair and try to fall asleep if it is possible.
- It is important that your child sit still if they cannot fall asleep during the testing.
- Your child will hear sounds sent through the implant. Your child can ignore these sounds.
- This test will take up to two hours.

_____ *(Initials)* Yes, I give permission for my child to participate in the auditory brainstem response section.

☐ **Auditory compound action potentials with a cochlear implant**:

- For this test, your child will sit in a comfortable chair.
- Your child can choose to watch a silent movie, read a book, or play games with an iPad.
- Your child will hear sounds through the implant. Your child can ignore these sounds.
- This test takes several hours to complete.
    - We will break it into sessions of 4 hours each.
    - It will take up to 3 sessions to complete.

_____ *(Initials)* Yes, I give permission for my child to participate in the auditory compound action potentials section.

☐ ***Psychophysical testing of auditory perception***:

- For this test, your child will sit in a comfortable chair.
- Your child will hear sounds through a loudspeaker or an earphone.
    - In one task, your child will repeat some words that they hear
    - In another task, your child will identify a short silence within a sound.

- This test will take up to two hours.

_____ *(Initials)* Yes, I give permission for my child to participate in the auditory compound action potentials section.

□ **Psychophysical testing of speech perception**:

- For this test, your child will sit in a comfortable chair.
- Your child will hear sounds through a loudspeaker or directly through your cochlear implant via an audio cable connection between your cochlear implant sound processor and the sound source.
- Your child will be asked to repeat some words that they hear.
- This test will take up to two hours.

_____ *(Initials)* Yes, I give permission for my child to participate in the psychophysical testing of speech perception section.

Tests used in this study may provide information that we were not specifically looking for in this study. This information is called "incidental findings". We will discuss these results with you if we believe that they may have an impact on your child's health. If you ask us to do so, we can also help you set up follow-up meetings with your child's regular doctor or other medical professionals not involved in a study who can discuss this information with you. These follow-up visits will not be part of this study. Therefore, you and your insurance company would be responsible for any fees and costs related to them.

4. How long will my child be in the study?

You may choose which tests to participate in from the assigned testing designated by the research team. Each child may participate in up to 5 tests. Each test session will take between 1 and 3 hours to complete. Testing may be completed over multiple visits.

5. Can my child stop being in the study?

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University and Nationwide Children's Hospital.

6. What risks, side effects or discomforts can my child expect from being in the study?

- We believe that there is very little chance that bad things will happen as a result of being in this study.
- There are no known risks from these non-invasive tests that have been used in hearing clinics for many years. However, there may be other risks of being in this research study that are not known at this time.

- Our research team will closely monitor your child, and we will immediately stop all tests if your child shows any signs of discomfort.
- We will give your child breaks throughout the testing and your child can ask for a break anytime.
- Please tell the researcher if you believe your child ever feels uncomfortable.
- It is possible that your child could feel upset when answering questions about their diagnosis or medical treatment, but it may be more likely that you and your child find the questions or feedback process a little boring. If your child does find any of the questions upsetting or does not want to answer a question, they do not have to, and the study team will be available to discuss this with you and your child further.
- Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

7. What benefits can my child expect from being in the study?

For cochlear implant and hearing aid users, possible benefits to your child might be a better understanding of factors attributing to his/her hearing performance. For all participants, the benefit is that we might learn something that could help people with hearing loss.

8. What other choices does my child have if he/she does not take part in the study?

You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my child's study-related information be kept private?

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law.

Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

You will also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your child's protected health information. Basic demographic information (gender, age), medical history, hearing tests, and implant information may be collected from your child's medical record or implant manufacturer databases.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

For listeners who are recruited as part of a clinical trial investigating auditory neural function in patients with Usher Syndrome, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

10. What are the costs of taking part in this study?

There is no additional cost other than traveling to our laboratory for participating this study.

11. Will I or my child be paid for taking part in this study?

For you and your child's time and inconvenience, your child (study participant) will receive $20/hour up to a total of $160/day. For listeners who participate in multiple testing

sessions scheduled in two consecutive days, we will provide up to $200.00 in reimbursement to help with travel costs.

By law, payments to subjects are considered taxable income.

12. What happens if my child is injured because he/she took part in this study?

All research involves a chance that something bad might happen to your child. This may include the risk of personal injury. In spite of all safety measures, your child might develop a reaction or injury from being in this study. If such problems occur, the researchers will help your child get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The Ohio State University and Nationwide Children's Hospital have not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

13. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact any of the following research team members:

- Dr. Shuman He at 614-293-5963

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-625.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Shuman He at 614-293-5963.

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	
Printed name of person authorized to provide permission for subject	**Signature of person authorized to provide permission for subject**
Relationship to the subject	**Date and time** **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	Date and time **AM/PM**
Printed name of witness	**Signature of witness**
	Date and time **AM/PM**

The Ohio State University and Nationwide Children's Hospital Consent to Participate in Research

Study Title: **Auditory Function in Children**

Principal Investigator: **Shuman He**

Sponsor: **National Institutes of Health**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University, or Nationwide Children's Hospital. If you are a student or employee at Ohio State (OSU), or Nationwide Children's Hospital (NCH) your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to learn about what responses or reactions people have when hearing different sounds. Currently, how well human listeners can encode (convert environmental sounds into meaningful hearing information that can be understood by listeners) different sounds is not well understood. A better understanding of this will allow us to provide the best care for people with hearing loss. This study is designed to address this knowledge gap.

2. How many people will take part in this study?

Overall, 390 participants will take part in this study.

3. What will happen if I take part in this study?

We will ask you to take part in up to 6 listening and/or behavioral tests.

- Each test measures a different area of the hearing system.
- Some tests compare what you heard (psychophysical) to how your hearing system reacted.
- We are asking you to take part in the tests below that have been checked by the researcher.
- We will ask you to write your initials after each test description that is checked, if you agree to participate in that test.

□ **Cortically evoked auditory potentials without a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your scalp.
- We will also place foam-tipped earphones in your ears.
- You will sit quietly in a comfortable chair and watch a silent movie.
- It is important that you sit still and relax while watching a movie, but that you do not fall asleep.
- Although you will be watching a silent movie, you will hear sounds in your ears. You can ignore these sounds.
- We will test up to 3 stimulation conditions.
- It will take up to 3 hours to finish each stimulation condition.

_____ *(Initials)* Yes, I will participate in the cortically evoked auditory potentials test.

□ **Cortically evoked auditory potentials with a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your scalp.
- You will sit quietly in a comfortable chair and watch a silent movie.
- It is important that you sit still and relax while watching a movie, but that you do not fall asleep.
- Although you will be watching a silent movie, you will hear sounds in your ears through the cochlear implant. You can ignore these sounds.
- We will test up to 4 types of sounds.
- It will take up to 3 hours to test each type of sound.

_____ *(Initials)* Yes, I will participate in the cortically evoked auditory potentials section.

□ **Auditory brainstem response without a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on your scalp.
- We will also place foam-tipped earphones in your ears.
- You will sit quietly in a comfortable chair and try to fall asleep if it is possible.
- It is important that you sit still if you cannot fall asleep during the testing.
- You will hear sounds in your ears. You can ignore these sounds.

- This test will take up to two hours.

_____ *(Initials)* Yes, I will participate in the auditory brainstem response section.

□ **Auditory brainstem responses with a cochlear implant**:

- For this test, we will place sticky tab electrodes at several places on you scalp.
- You will sit quietly in a comfortable chair and try to fall asleep if it is possible.
- It is important that you sit still if you cannot fall asleep during the testing.
- You will hear sounds sent through the implant. You can ignore these sounds.
- This test will take up to two hours.

_____ *(Initials)* Yes, I will participate in the auditory brainstem response section.

□ **Auditory compound action potentials with a cochlear implant**:

- For this test, you will sit in a comfortable chair.
- You can choose to watch a silent movie, read a book, or play games with an iPad.
- You will hear sounds through the implant. You can ignore these sounds.
- This test takes several hours to complete.
    - We will break it into sessions of 4 hours each.
    - It will take up to 3 sessions to complete.

_____ *(Initials)* Yes, I will participate in the auditory compound action potentials section.

□ ***Psychophysical testing of auditory perception***:

- For this test, you will sit in a comfortable chair.
- You will hear sounds through a loudspeaker or an earphone.
    - In one task, you will repeat some words that they hear.
    - In another task, you will identify a short silence within a sound.
- This test will take up to two hours.

_____ *(Initials)* Yes, I will participate in the auditory compound action potentials section.

□ **Psychophysical testing of speech perception**:

- For this test, you will sit in a comfortable chair.
- You will hear sounds through a loudspeaker or directly through your cochlear implant via an audio cable connection between your cochlear implant sound processor and the sound source.
- You will be asked to repeat some words that you will hear.
- This test will take up to two hours.

_____ *(Initials)* Yes, I will participate in the psychophysical testing of speech perception section.

Tests used in this study may provide information that we were not specifically looking for in this study. This information is called “incidental findings”. We will discuss these results with you if we believe that they may have an impact on your health. If you ask us to do so, we can also help you set up follow-up meetings with your regular doctor or other medical professionals not involved in a study who can discuss this information with you. These

follow-up visits will not be part of this study. Therefore, you and your insurance company would be responsible for any fees and costs related to them.

4. How long will I be in the study?

You may choose which tests to participate in from the assigned testing designated by the research team. Each individual may participate in up to 5 tests. Each test session will take between 1 and 3 hours to complete. Testing may be completed over multiple visits.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University, or Nationwide Children's Hospital.

6. What risks, side effects or discomforts can I expect from being in the study?

- We believe that there is very little chance that bad things will happen as a result of being in this study.
- There are no known risks from these non-invasive tests that have been used in hearing clinics for many years. However, there may be other risks of being in this research study that are not known at this time.
- Our research team will closely monitor you, and we will immediately stop all tests if you shows any signs of discomfort.
- We will give you breaks throughout the testing and you can ask for a break anytime.
- Please tell the researcher if you ever feel uncomfortable.
- It is possible that you could feel upset when answering case history questions about your diagnosis or medical treatment, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or do not want to answer a question, you do not have to, and the study team will be available to discuss this with you further.
- Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

7. What benefits can I expect from being in the study?

For cochlear implant and hearing aid users, possible benefits to you might be a better understanding of factors attributing to your hearing performance. For all participants, the benefit is that we might learn something that could help people with hearing loss.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There is no additional cost other than traveling to our laboratory for participating this study.

10. Will I be paid for taking part in this study?

For your time and inconvenience, you will receive $20/hour up to a total of $160/day. For listeners who participate in multiple testing sessions scheduled in two consecutive days, we will provide up to $200.00 in reimbursement to help with travel costs.

By law, payments to subjects are considered taxable income.

11. What happens if I am injured because I took part in this study?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The Ohio State University, and Nationwide Children's Hospital have not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

You will also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information. Basic demographic information (gender, age), medical history, hearing tests, and implant information may be collected from your medical record or implant manufacturer databases.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

For listeners who are recruited as part of a clinical trial investigating auditory neural function in patients with Usher Syndrome, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact any of the following individuals:

- Dr. Shuman He at 614-293-5963

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Shuman He at 614-293-5963.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this consent form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM **Date and time**
Printed name of witness	**Signature of witness**
	AM/PM **Date and time**