

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?

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

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**Name of Child:** \_\_\_\_\_

Yes       No

*research procedures.)*

**Parental Permission on File:**

*(If "No," do not proceed with assent or*

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

**Signature of Researcher:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**(Optional) Signature of Child:** \_\_\_\_\_

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2 **The Ohio State University and Nationwide Children's Hospital**

3 **Assent to Participate in Research**

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5 **Study Title:** **Auditory Function in Children**

6 **Principal Investigator:** **Shuman He**

7 **Sponsor:** **National Institutes of Health**

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- 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.

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18 **1. What is this study about?**

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20 The purpose of this study is to learn about what responses or reactions people have when

21 hearing different sounds. How well human listeners can encode (change environmental

22 sounds into meaningful hearing information that can be understood by listeners) and

23 understand different sounds is not well understood. A better understanding of this will

24 allow us to provide better care for people with hearing loss.

25

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

27

28 In one part of this study, you will either sit in a comfortable chair and watch a silent

29 movie, or play with an iPad. You do not need to pay attention to the sounds that you will

30 hear for this part of the study. You may have medical stickers placed on your face and

31 head. These do not hurt, but are just stickers that help us know what your brain or your

32 nerves are doing. If you need a break anytime, just tell us.

33 In the second part of this study, you will sit in a comfortable chair. You may be asked to

34 tell us whether the sound is too loud, repeat some words or sentences you hear, or to select

35 a sound that sounds different to you. If you need a break anytime, just tell us.

36

37 **3. How long will I be in the study?**

38

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

42

43 **4. Can I stop being in the study?**

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45 You may stop being in the study at any time.

46

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

48

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

52

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

54

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

57

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

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60 You will be paid to be in this study.

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62 **8. Who can I talk to about the study?**

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

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- Dr. Shuman He at 614-293-5963

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

70

71 **Signing the assent form**

72  
73  
74 I have read (or someone has read to me) this form. I have had a chance to ask questions  
75 before making up my mind. I want to be in this research study.  
76  
77

AM/PM

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Signature or printed name of subject

Date and time

82 **Investigator/Research Staff**

83  
84 I have explained the research to the participant before requesting the signature above. There  
85 are no blanks in this document. A copy of this form has been given to the participant or  
86 his/her representative.  
87

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Printed name of person obtaining assent

Signature of person obtaining assent

AM/PM

---

Date and time

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

1  
2 **The Ohio State University and Nationwide Children's Hospital**  
3 **Parental Permission**  
4 **For Child's Participation in Research**  
5  
6

**Study Title:** **Auditory Function in Children**

**Principal Investigator:** **Shuman He**

**Sponsor:** **National Institutes of Health**

7  
8 • **This is a parental permission form for research participation.** It contains important  
9 information about this study and what to expect if you permit your child to participate.  
10 Please consider the information carefully. Feel free to discuss the study with your friends  
11 and family and to ask questions before making your decision whether or not to permit  
12 your child to participate.  
13 • **Your child's participation is voluntary.** You or your child may refuse participation in  
14 this study. If your child takes part in the study, you or your child may decide to leave the  
15 study at any time. No matter what decision you make, there will be no penalty to your  
16 child and neither you nor your child will lose any of your usual benefits. Your decision  
17 will not affect your future relationship with The Ohio State University or Nationwide  
18 Children's Hospital. If you or your child is a student or employee at Ohio State (OSU) or  
19 Nationwide Children's Hospital (NCH) your decision will not affect your grades or  
20 employment status.  
21 • **Your child may or may not benefit as a result of participating in this study.** Also, as  
22 explained below, your child's participation may result in unintended or harmful effects for  
23 him or her that may be minor or may be serious depending on the nature of the research.  
24 • **You and your child will be provided with any new information that develops during  
25 the study that may affect your decision whether or not to continue to participate.** If  
26 you permit your child to participate, you will be asked to sign this form and will receive a  
27 copy of the form. You are being asked to consider permitting your child to participate in  
28 this study for the reasons explained below.  
29  
30

31 **1. Why is this study being done?**

32  
33 The purpose of this study is to learn about what responses or reactions people have when  
34 hearing different sounds. Currently, how well human listeners can encode (convert  
35 environmental sounds into meaningful hearing information that can be understood by

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

39

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

41 Overall, 390 participants will take part in this study.

42

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

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

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

52

### 53 **Cortically evoked auditory potentials without a cochlear implant:**

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

64 \_\_\_\_\_ (Initials) Yes, I give permission for my child to participate in the cortically evoked  
65 auditory potentials test.

66

### 67 **Cortically evoked auditory potentials with a cochlear implant:**

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

77 \_\_\_\_\_ (Initials) Yes, I give permission for my child to participate in the cortically evoked

80                   auditory potentials section.

81

82

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

84                   • For this test, we will place sticky tab electrodes at several places on your child's  
85                   scalp.

86                   • We will also place foam-tipped earphones in your child's ears.

87                   • Your child will sit quietly in a comfortable chair and try to fall asleep if it is  
88                   possible.

89                   • It is important that your child sit still if they cannot fall asleep during the testing.

90                   • Your child will hear sounds in their ears. They can ignore these sounds.

91                   • This test will take up to two hours.

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

94

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

96                   • For this test, we will place sticky tab electrodes at several places on your child's  
97                   scalp.

98                   • Your child will sit quietly in a comfortable chair and try to fall asleep if it is  
99                   possible.

100                   • It is important that your child sit still if they cannot fall asleep during the testing.

101                   • Your child will hear sounds sent through the implant. Your child can ignore these  
102                   sounds.

103                   • This test will take up to two hours.

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

106

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

108                   • For this test, your child will sit in a comfortable chair.

109                   • Your child can choose to watch a silent movie, read a book, or play games with an  
110                   iPad.

111                   • Your child will hear sounds through the implant. Your child can ignore these  
112                   sounds.

113                   • This test takes several hours to complete.

- 114                    ○ We will break it into sessions of 4 hours each.
- 115                    ○ It will take up to 3 sessions to complete.

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

118

119                    **Psychophysical testing of auditory perception:**

120                   • For this test, your child will sit in a comfortable chair.

121                   • Your child will hear sounds through a loudspeaker or an earphone.

- 122                    ○ In one task, your child will repeat some words that they hear
- 123                    ○ In another task, your child will identify a short silence within a sound.

124     • This test will take up to two hours.

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

128     □ **Psychophysical testing of speech perception:**

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

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

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

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

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

152     **5. Can my child stop being in the study?**

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

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

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

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

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

180  
181 For cochlear implant and hearing aid users, possible benefits to your child might be a  
182 better understanding of factors attributing to his/her hearing performance. For all  
183 participants, the benefit is that we might learn something that could help people with  
184 hearing loss.

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

188  
189 You or your child may choose not to participate without penalty or loss of benefits to  
190 which you are otherwise entitled.

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

193  
194 Efforts will be made to keep your child's study-related information confidential.  
195 However, there may be circumstances where this information must be released. For  
196 example, personal information regarding your child's participation in this study may be  
197 disclosed if required by state law.

198  
199 Also, your child's records may be reviewed by the following groups (as applicable to the  
200 research):

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

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

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

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

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

230 Please talk to your study team, or contact the Office of Responsible Research Practices at  
231 614-688-8641, if you have questions.

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

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

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

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

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

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

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

251  
252 By law, payments to subjects are considered taxable income.  
253

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

255  
256 All research involves a chance that something bad might happen to your child. This may  
257 include the risk of personal injury. In spite of all safety measures, your child might  
258 develop a reaction or injury from being in this study. If such problems occur, the  
259 researchers will help your child get medical care, but any costs for the medical care will  
260 be billed to you and/or your insurance company. The Ohio State University and  
261 Nationwide Children's Hospital have not set aside funds to pay you for any such reactions  
262 or injuries, or for the related medical care. You do not give up any of your legal rights by  
263 signing this form.

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

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

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

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

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

## 277 **14. Who can answer my questions about the study?**

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

280 - Dr. Shuman He at 614-293-5963

281 For questions about your child's rights as a participant in this study or to discuss other  
282 study-related concerns or complaints with someone who is not part of the research team,  
283 you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at  
284 1-800-678-625.

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

296  
297  
298

299 **Signing the parental permission form**

300  
301 I have read (or someone has read to me) this form and I am aware that I am being asked to  
302 provide permission for my child to participate in a research study. I have had the opportunity  
303 to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit  
304 my child to participate in this study.

305  
306 I am not giving up any legal rights by signing this form. I will be given a copy of this form.  
307

---

Printed name of subject

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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

308  
309 **Investigator/Research Staff**

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

---

Printed name of person obtaining consent

---

Signature of person obtaining consent

---

AM/PM

---

Date and time

316  
317 **Witness(es) - May be left blank if not required by the IRB**

318  
319

---

Printed name of witness

---

Signature of witness

---

AM/PM

---

Date and time

---

Printed name of witness

---

Signature of witness

---

AM/PM

---

Date and time

320

1

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

4 **Study Title:** **Auditory Function in Children**

5 **Principal Investigator:** **Shuman He**

6 **Sponsor:** **National Institutes of Health**

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- **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?**

36  
37      Overall, 390 participants will take part in this study.  
38

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

40      We will ask you to take part in up to 6 listening and/or behavioral tests.  
41      • Each test measures a different area of the hearing system.  
42      • Some tests compare what you heard (psychophysical) to how your hearing system  
43      reacted.  
44      • We are asking you to take part in the tests below that have been checked by the  
45      researcher.  
46      • We will ask you to write your initials after each test description that is checked, if  
47      you agree to participate in that test.  
48

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

50      • For this test, we will place sticky tab electrodes at several places on your scalp.  
51      • We will also place foam-tipped earphones in your ears.  
52      • You will sit quietly in a comfortable chair and watch a silent movie.  
53      • It is important that you sit still and relax while watching a movie, but that you do  
54      not fall asleep.  
55      • Although you will be watching a silent movie, you will hear sounds in your ears.  
56      You can ignore these sounds.  
57      • We will test up to 3 stimulation conditions.  
58      • It will take up to 3 hours to finish each stimulation condition.  
59

60      (Initials) Yes, I will participate in the cortically evoked auditory potentials test.  
61

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

63      • For this test, we will place sticky tab electrodes at several places on your scalp.  
64      • You will sit quietly in a comfortable chair and watch a silent movie.  
65      • It is important that you sit still and relax while watching a movie, but that you do  
66      not fall asleep.  
67      • Although you will be watching a silent movie, you will hear sounds in your ears  
68      through the cochlear implant. You can ignore these sounds.  
69      • We will test up to 4 types of sounds.  
70      • It will take up to 3 hours to test each type of sound.  
71

72      (Initials) Yes, I will participate in the cortically evoked auditory potentials section.  
73

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

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

80     • This test will take up to two hours.

81     \_\_\_\_\_ (Initials) Yes, I will participate in the auditory brainstem response section.

82

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

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

89     \_\_\_\_\_ (Initials) Yes, I will participate in the auditory brainstem response section.

90

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

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

98     \_\_\_\_\_ (Initials) Yes, I will participate in the auditory compound action potentials section.

99

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

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

106     \_\_\_\_\_ (Initials) Yes, I will participate in the auditory compound action potentials section.

107

108     □ **Psychophysical testing of speech perception:**

- 109       • For this test, you will sit in a comfortable chair.
- 110       • 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.
- 111       • You will be asked to repeat some words that you will hear.
- 112       • This test will take up to two hours.

113     \_\_\_\_\_ (Initials) Yes, I will participate in the psychophysical testing of speech perception section.

114     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

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

127 **4. How long will I be in the study?**

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

133 **5. Can I stop being in the study?**

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

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

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

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

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

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

166  
167 You may choose not to participate without penalty or loss of benefits to which you are  
168 otherwise entitled.

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

171  
172 There is no additional cost other than traveling to our laboratory for participating this  
173 study.

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

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

181 By law, payments to subjects are considered taxable income.

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

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

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

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

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

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

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

210  
211 **13. Will my study-related information be kept confidential?**  
212

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

217  
218 Also, your records may be reviewed by the following groups (as applicable to the  
219 research):

220

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

226  
227 You will also be asked to sign a separate Health Insurance Portability and Accountability  
228 Act (HIPAA) research authorization form if the study involves the use of your protected  
229 health information. Basic demographic information (gender, age), medical history, hearing  
230 tests, and implant information may be collected from your medical record or implant  
231 manufacturer databases.

232  
233 The NIH has issued a Certificate of Confidentiality for this study. This Certificate  
234 provides extra protection for you and your study information, documents, or samples  
235 (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose  
236 any identifiable, sensitive information collected about you as a part of this study in a  
237 lawsuit or legal proceeding. We are also prevented from releasing your study information  
238 without your consent. This is a layer of protection over and above the already existing  
239 protections in place for you and your information, documents, or samples.

240  
241 However, these protections do not apply in some situations. For example, we may have to  
242 release your information if a law requires us to do so, the Agency that is funding this  
243 study requests the information, or if the FDA tells us to release this information. We may  
244 also use your information to conduct other scientific research as allowed by federal  
regulations.

245  
246 Study information that has health implications may be placed in your medical record  
247 where authorized employees may see the information. Further, authorized requests for  
248 your records (medical record release for continuity of care) may result in research-related  
information being released.

249  
250 Please talk to your study team, or contact the Office of Responsible Research Practices at  
614-688-8641, if you have questions.

251 You may also visit the NIH website at <https://humanSubjects.nih.gov/coc/faqs> to learn  
252 more.

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

259 **14. Who can answer my questions about the study?**

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

264 - Dr. Shuman He at 614-293-5963

266 For questions about your rights as a participant in this study or to discuss other study-  
267 related concerns or complaints with someone who is not part of the research team, you  
268 may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-  
269 800-678-6251.

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

275 **Signing the consent form**

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

280 I am not giving up any legal rights by signing this form. I will be given a copy of this consent  
281 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	

283 **Investigator/Research Staff**

286 I have explained the research to the participant or his/her representative before requesting the  
287 signature(s) above. There are no blanks in this document. A copy of this form has been given  
288 to the participant or his/her representative.  
289

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

290  
291 **Witness(es)** - *May be left blank if not required by the IRB*  
292

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

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

293