

## **Participant Information Sheet – Parent/Carer**

Study title: New Tests for Remote Monitoring of Cochlear Implants

Principal Investigator: Helen Cullington

Investigation Site: Southampton

Site Principal Investigator: Helen Cullington

**Please read this information carefully before deciding if you want your child to take part in this research. Please talk to your child about the project at a level appropriate for them, and ask them if they would like to do it. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your child will take part, you might want to talk about it with a relative, friend or your local doctor. Feel free to do this. If you are happy for your child to participate you will be asked to sign a consent form, and your child may fill in an assent form. You will be given a copy of this Participant Information Sheet and consent form and assent form to keep.**

### **What is the research about?**

Your child is invited to take part in a research study that will try out a new set of tests that could be used by clinicians to work out if someone using a cochlear implant needs to come to the cochlear implant centre. The research is sponsored by the company that made your child's implant: Cochlear. We want to know how people using implants and their carers feel about these tests. We will also ask clinicians if there is anything else they need in order to decide if someone needs to the cochlear implant centre or not.

Coming to the cochlear implant centre can be expensive for some people, and can mean time off work or school for people using implants and their families. We would like to have some tools that people using implants and their carers could have at home so they could send the results to the clinician to see if they need to come to the centre or not. It could also help clinicians decide how long an appointment should be.

The tests are very similar to those your child may do in the clinic: a hearing test, speech understanding test using numbers, telemetry and data logging (checking the internal implant) and some questionnaires. Some will be done on an iPad and some using the usual software the audiologists use: Custom Sound.

### **Why has my child been invited?**

Your child has been invited to take part in this research project because your child has a Cochlear Limited cochlear implant generation 4 or above, uses a CP900 series sound processor, and is 4 years old or above.

**What does the project involve?**

The project involves your child doing the new tests before their appointment with the audiologist. The audiologist will then look at the results and see if they give enough information to decide what your child needs help with. Your child will then still have their usual appointment with the audiologist.

**What exactly will happen to my child if she/he takes part?**

If you want your child to take part, all the study testing would happen just before your child's next appointment; you would need to come 30 minutes early.

Your child will do the new tests before seeing the audiologist. Your child will use a direct connect lead to an iPad and computer so that your child can listen without hearing outside sounds. Your child will have help doing the tests and getting connected. The tests are:

1. Digit Triplet Test: a hearing test listening to numbers and repeating them
2. aided thresholds: listening and responding to quiet beeps, like your child does in the clinic
3. telemetry: checking of the internal implant, like the audiologist does in clinic, including downloading settings from the speech processor, for example how much your child has worn the processor. The audiologist always does this in clinic too
4. filling in a questionnaire about how you are feeling about your child's hearing, how much your child uses the processor, and if there is anything your child needs help with. We also will ask you how old your child is, how long it took you to get to clinic, and how much it cost, and how you and your child feel about the new tests.
5. the tester will take a photo of your child's implant site behind the ear

If your child has two cochlear implants, we will try and get as much testing done on each ear separately (like the audiologist does), but we are happy to give up if your child loses interest! The audiologist will then look at these results and fill in a questionnaire about whether the results would be enough to decide what sort of appointment (if any) was needed.

***Your child will then have the usual appointment with the audiologist***

The audiologist will note down what was done in the appointment and why.

**Are there any benefits in my child taking part?**

There will not be any direct benefits to your child if you take part. However it may enable us to improve our service for people with cochlear implants in the future.

**Are there any risks involved?**

New speech testing software will be used to deliver the sounds for the tests. As with any software, there is a small risk of hearing sounds that are uncomfortably loud. If this happens, you can stop the sound immediately by taking off the speech processor coil/headpiece. The tester will watch your child carefully in case it gets too loud.

If you or your child wish to stop the project at any point, just let us know. You don't have to say why.

**Costs**

Participation in this study will not cost you anything, and you will not be paid.

**Will my child's participation be confidential?**

Participation in the study will be kept confidential, all the information collected from your child for the study will be treated confidentially. All data will be secured against unauthorised access. Your child's privacy and confidentiality of their information will be preserved in reports and when publishing any data.

Both Cochlear and the Investigators named above will have access to the information collected from your child for the study. Regulatory authorities, Ethics Committee representatives and sponsor's representatives involved in the clinical investigation will have direct access to source data during and after the clinical investigation for Sponsor monitoring, audits, Ethics Committee review and regulatory authority inspections.

The study results may be presented at a conference or in a scientific publication, but we will not use your child's name or any other details that people could use to work out who your child is.

You can have a summary of the findings; please ask Helen Cullington (023 80 597606, [H.Cullington@Southampton.ac.uk](mailto:H.Cullington@Southampton.ac.uk)).

**What is Cochlear's role in the project?**

Cochlear is the company that made your child's implant. They are sponsoring this study. Throughout the study, people who work for the company Cochlear will visit the investigation sites, for investigator training and monitoring and audit of the study (check data entry).

The study will be conducted in accordance to ISO14155 and Good Clinical Practice in Research; the Cochlear staff will make sure these rules are followed. You can have a list of Cochlear staff and their duties if you would like this. The data collected in this

study will be used for internal communication, product training and product launch materials.

Cochlear may stop the project if the investigators are not following the study protocol or for any other reason.

**What happens if I change my mind or my child doesn't want to do it any more?**

It is totally up to you and your child whether your child takes part or not. Whether your child takes part or not will not affect your child's clinical care or relationship with the company Cochlear in any way. You and your child are free to leave the study at any point without telling us why.

Sometimes during the course of a study, new information becomes available. While your child is participating in this study, you and your child will be kept informed in writing of any significant new findings which may affect your willingness to continue in the study.

**What happens if something goes wrong?**

In the unlikely case of concern or complaint, you should contact the Research Governance Office:

**Research Governance Office**  
**George Thomas Building 37**  
**Room 4079**  
**University of Southampton**  
**Highfield**  
**Southampton SO17 1BJ**

Tel: 02380 595058

[rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)

Please note that the researcher or others persons involved in the study will not deal with any complaints.

You can also contact Cochlear at any time:

Lisa De Bold	+447918741224	<a href="mailto:ldebold@cochlear.com">ldebold@cochlear.com</a>
Saji Maruthurkkara	+6129425-3637	<a href="mailto:smaruthurkkara@cochlear.com">smaruthurkkara@cochlear.com</a>

You can also contact the Patient Advice and Liaison Service (PALS)

023 8120 8498

[patientsupportservices@uhs.nhs.uk](mailto:patientsupportservices@uhs.nhs.uk)

**Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect you and your child's interests. This study has

been reviewed and given a favourable opinion by the East of England -  
Cambridgeshire and Hertfordshire Research Ethics Committee.

**Where can I get more information?**

You can contact:

**Dr Helen Cullington (Principal Investigator, University of Southampton  
Auditory Implant Service)**

H.Cullington@Southampton.ac.uk

023 80 597606

or Cochlear:

Lisa De Bold

+447918741224

ldebold@cochlear.com

Saji Maruthurkkara

+6129425-3637

smaruthurkkara@cochlear.com