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**Participant Information Sheet**

**Study Title: The correlation between temporal properties of the auditory nerve and auditory perception abilities in cochlear implant users.**

**Invitation**

We would like to invite you to take part in our research study. Before you decide whether or not to take part, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if youtake part. Part 2 gives you more detailed information about the conduct of the study.

**One of our team is always available to go through the information sheet with you and answer any questions you have.**

Sharmila Patel is the research audiologist who will be leading this project and you should contact her if there is anything that is not clear. Contact details for Sharmila are at the end of this information sheet.

**PART 1**

**What is the purpose of the study?**

We would like to see how your hearing nerve responds to the sounds provided by your cochlear implant. Everyone’s hearing nerve takes a different amount of time to respond to the sounds they hear through a cochlear implant; this timing information about the hearing nerve may help us programme cochlear implants better which may result in better performance in cochlear implant users. There is currently a lack of evidence in this area and we hope this study will help us fill in some of the gaps in the current research.

**Why have I been invited?**

You have been invited because you are a cochlear implant user.

**Do we have to take part?**

No, it is up to you to decide whether or not to join the study. We are available to describe the study to you and go through this information sheet with you before you make any decision to be involved. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive from the cochlear implant service.

**What will happen to me if I agree to take part?**

You will only need to attend for one appointment. The appointment will last approximately 1-2 hours. The following will take place at this appointment. Research appointment:

Appointment (1-2 hours)

Timing information from your hearing nerve will be obtained through a speech processor (not your own speech processor). This information will be obtained using standard clinical tests

Following this test you will be asked to complete a speech test and a test to check how you process the timing between sounds.

The testing will occur at St Georges Hospital. Each appointment will take between one to two hours including breaks. We will arrange the appointment on a day which is convenient for you.

We will be able to debrief you on the results of the tests following the appointment if you wish to have this information.

**What will I have to do?**

At the appointment we will perform a standard clinical test; which will give us information on how the hearing nerves timing works in response to sound. You will be asked to sit in a comfortable chair and in the initial part of the test and we will play some sounds through the processor at different electrodes (4 in total) you can bring a book or paper to read for this portion of the test.

After this test you will be asked to complete a standard clinical test where we will ask you to detect a gap in between sounds, which are presented through a speaker in a clinic room. You will also be asked to listen to lists of words and repeat what you hear.

**What are the possible disadvantages and risks of taking part?**

The study does not require any changes to the clinical management you would undergo if you were not participating in the study. All testing is non-invasive and all the equipment used is compatible with your cochlear implant. For this reason there is no additional risk incurred by agreeing to participate.

We consider there is minimal disadvantage due to the inconvenience of attending the hospital for additional appointments than you would normally do and the appointments being approximately 1-2 hours.

**What are the possible benefits of taking part?**

We cannot promise that the study will help you but the information we get will help inform clinicians about the relationship between refractory properties and temporal coding, hearing outcomes with a cochlear implant and guiding programming of cochlear implants. This information may ultimately benefit all individuals with cochlear implants.

**What if there is a problem?**

Any compliant about the way you have been dealt with during the study or any adverse effect on you caused by the study will be addressed. Detailed information is given in Part 2.

**Will my taking part in the study be kept confidential?**

Yes we will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

**This completes Part 1 of the Information Sheet**

**If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.**

**Your GP will be informed that you have consented to take part in this study.**

**PART 2**

**What will happen to me if I take part?**

How long will the study go on for?

You will be involved in the study for approximately 6-8 months

**What if new information becomes available?**

Sometimes during the course of a clinical study, new information becomes available about the device being studied. If this happens and it is relevant to you, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your clinical care will continue as usual. If you decide to continue in the study you will be asked to sign an updated consent form.

What will happen if I don’t want to carry on with the study?

You may withdraw from the study at any time and without giving a reason. If you withdraw, we would like to use anonymised research data that we have gathered from you up to that point.

**What if there is a problem?**

If you have any concern about any aspect of this study, you should contact Sharmila Patel (Sharmilapatel@nhs.net, 0208 725 4563) who will do her best to answer your questions.

If you wish to complain, or have any concerns about your involvement in the study you can contact the Patient Advice and Liaison Service at St Georges Healthcare NHS Trust Blackshaw Road, London, SW17 0QT, Tel: 020 8725 2453

**Will taking part in this study be kept confidential?**

Any information which you give to the research team and all the measurements that are collected from you will be confidential. Parts of your medical records and the data collected for the study will be reviewed by the research team. All members of the research team will have a duty of confidentiality to you and nothing that could reveal your identity will be disclosed outside the research team, without your permission. Data collected will be stored in locked filing cabinets and password protected secure computers. Names and address will be stored separately to other data and no names will be used when the research is written up. Your results will be kept for 10 years and will then be destroyed. The handling, processing, storage and destruction of their data will be in accordance with the UK Data Protection Act 1998 and St Georges Healthcare NHS Trust’s Data Protection Policy.

**What will happen to the results of the research study?**

We shall report the results at medical and scientific meetings and in medical and scientific journals. We will send you a one-page summary of the results of the study if you wish. Your identity will not be disclosed when we report the results of the study.

**Who is organising and funding the research?**

The research is organised by the University of Southampton. None of the researchers nor their institutions, will be paid for including you in the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been approved by the University of Southampton Ethics Board and St Georges Hospital Medical School Ethics Committee.

What should I do next?

Please read the consent form that is attached at the end of the information sheet. We will give you copies of these documents to take home. If you would like to take part, please complete the consent form and hand in or post to Sharmila Patel, Auditory Implant Service, St Georges Hospital, Blackshaw Road, SW17 0QT or bring it with you at your appointment with us. If you would like more information, please get in touch with Sharmila Patel. She can be reached by telephone on 020 8725 4563 or email at sharmilapatel@nhd.net.

**Thank you for considering taking part in this study.**